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**Rehabilitation of executive function deficits following acquired brain injury: a
randomised controlled trial using Goal Management Training and Implementation**

Intentions to improve prospective memory

and

Clinical Research Portfolio

VOLUME I

(VOLUME II Bound Separately)

Andrew Wood

July 2011

Academic Unit for Mental Health & Wellbeing

Faculty of Medicine Graduate School

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Registration number: 0200259

Thesis Title: REHABILITATION OF EXECUTIVE FUNCTIONN DEFICITS
FOLLOWING ACQUIRED BRAIN INJURY: A RANDOMISED CONTROLLED TRIAL
USING GOAL MANAGEMENT TRAINING AND IMPLEMENTATION INTENTIONS
TO IMPROVE PROSPECTIVE MEMORY

College: COLLEGE OF MEDICAL, VETERINARY AND LIFE SCIENCES

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Chapter 1: Systematic Review

A systematic review of questionnaire measures used to assess denial following acquired brain injury

Andrew Wood*
Academic Unit for Mental Health & Wellbeing

Keywords:

Unawareness; Denial; Anosognosia; Brain Injury; Neurological

*** Correspondence to:**

Andrew Wood
Academic Unit for Mental Health & Wellbeing
Academic Centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Abstract

Introduction: Unawareness of deficits is a common phenomenon following brain injury. The causes of unawareness are commonly attributed either to neurological (anosognosia) or psychological (denial) explanations. Anosognosia is the most frequently cited explanation for unawareness, although denial represents a plausible alternative given the traumatic and life-changing nature of sustaining a brain injury. Although denial is often mentioned in the literature, studies rarely conduct direct assessments to try and determine its presence. This review focuses on those measures which have been used to assess denial following brain injury, evaluating their methodological quality, as well as the extent to which they are capable of measuring this phenomenon.

Methods: Search terms were applied to electronic databases, and hand searches were conducted of relevant journals between 1990 and February 2010.

Results: Eight assessment measures were identified which had been used to directly assess the presence of denial following brain injury, focussing on participants' beliefs; behavioural observations; and implicit measures of denial and defensiveness.

Discussion: The methodological quality of assessment measures varied substantially. Many of the measures used to assess denial did not report basic psychometric properties. None of the studies control for potential confounds in criterion validity and conflation of behavioural responses with underlying constructs. There was no evidence of convergent validity between separate measures. Implicit measures were

viewed as the most psychometrically robust in this specific context. The clinical and ethical implications of assessing denial are discussed, along with methodological recommendations for future research.

Introduction

Unawareness of impairments is a common consequence of acquired brain injury. However, there is a central difficulty regarding terminology when exploring the literature in this area. The terms ‘unawareness’, ‘denial’ and ‘anosognosia’ are frequently used interchangeably. Sometimes the same term is used to describe different sorts of concepts and sometimes different terms are used to describe similar concepts (Markova & Berrios, 2006). This is further complicated by a lack of specificity with regard to the way in which these terms are applied. For example, they are often used to describe the *presence* of a particular behaviour (e.g. *denying* hemiplegia; *lacking insight* into cognitive deficits), as well as implying the *cause* of this behaviour (e.g. psychological vs. neurological factors). For the purposes of clarity, this review will adopt the same nomenclature as Kortte & Wegener (2004): ‘unawareness’ will be used to describe the presence of limited awareness or insight into impairments or into the implications of such impairments. In the context of acquired brain injury, ‘denial’ will be used to refer to unawareness presumed to be of psychological origin, and ‘anosognosia’ will refer to unawareness presumed to be of neurological origin.

Some authors have argued that the *presence* of unawareness is important because it has significant prognostic value in terms of vocational outcomes following acquired brain injury (e.g. Sherer, Hart, Todd, Whyte, Thompson et al., 2003). Markova & Berrios (2006) conducted a review of methods used to assess the presence and

extent of unawareness. They identified three main groups of assessment methods: clinician-rated; discrepancy methods; and composite methods. Clinician-rated methods rely on clinical judgements to determine the extent to which a patient lacks insight, and differences exist in terms of the factors that are examined in different studies. Discrepancy methods determine the level of insight according to the discrepancy between the patient's self-reported functioning and that of another individual, again focussing on a variety of different factors. Finally, composite measures represent a mixed group of methods, including combinations of clinician-rated and discrepancy methods (e.g. video-feedback and qualitative interviews).

Recent reviews have also explored the *causal* factors associated with unawareness. Orfei, Robinson, Prigatano, Starkstein, Rucsh et al. (2007) reviewed the neural correlates associated with *anosognosia*. They note that neuro-imaging studies indicate that anosognosia for hemiplegia is influenced by a number of factors, including lesion size and location. In particular, they highlight damage to fronto-parietal and fronto-parietal-temporal regions as playing a role in unawareness of hemiplegia. However, when considering these findings, it should be recognised that the method and manner of assessment has a significant influence on the degree to which unawareness is detected (Markova & Berrios, 2006; Yeates, Henwood, Gracey & Evans, 2006), and there may be a need to re-consider how unawareness is assessed both in clinical and research contexts.

Evidence from other clinical populations indicates that unawareness can also be a behavioural response to many serious or life-changing illnesses (Weinstein & Kahn, 1955), and in these situations unawareness is attributed to *psychological denial*. According to psychoanalytic theory, denial represents one of the serious forms of psychological defence, involving the distortion of significant aspects of internal and external reality (Leiper, 2007; pp. 57). It does not so much represent the *lack* of insight, but rather a motivated method of controlling distressing information about the self (Kortte & Wegener, 2004). However, recent theories have challenged this traditional psychodynamic conceptualisation of denial (Miller & Rollnick, 2002). These argue that denial is not so much driven by ego protection, but instead derives from discursive 'traps' in which the interlocutors engage (e.g. convincing, arguing for, blaming, shaming; see Medley & Powell (2010) for a conceptual review in the context of brain injury).

Generally any attempt to measure or identify the presence of one causal explanation of unawareness (anosognosia or denial) would by default be presumed to identify the presence or absence of the other. However, this assumption derives from the belief that anosognosia and denial are mutually exclusive (e.g. Levine, Calvani & Rinn, 1991), a conclusion for which there is little empirical support. More plausible is the view that denial and anosognosia may coexist in different proportions within a given individual (Prigatano & Klonoff, 1998) and thus either may be explored independently. Nonetheless, there is a substantial disparity in the volumes of research investigating these two causal explanations, with relatively few attempting

to assess psychological denial. This is partly a consequence of applying Occam's razor to the issue of unawareness following brain injury; given the sudden onset of unawareness following neurological insult, a neurological explanation represents the most parsimonious explanation. Where research has referred to denial, it has typically done so for the purposes of explaining other phenomena, such as the relationship between unawareness and depression (e.g. Anson & Ponsford, 2006).

However, perhaps more significant issues are the conceptual and clinical factors which undermine the validity of any attempt to assess denial in the context of acquired brain injury. The first issue is common to attempts to experimentally investigate psychodynamic concepts; that is, there is a need to ensure that participant's behavioural responses are actually linked to the proposed underlying construct. For example, Crombez, Beirens, Van Damme, Eccleston & Fontain (2009) noted that all the somatisation assessment scales which they reviewed assessed only somatic complaints, and did not link these with underlying psychological distress (which would have been predicted to occur by psychodynamic theory). Thus in relation to denial, unless evidence is provided to the contrary, statements such as "at first I had some problems, but now I'm fine" may only be measuring the behavioural phenomenon (unawareness) without identifying the cause (e.g. denial or anosognosia).

The second issue is unique to the measurement of denial following brain injury. Specifically, because the existence of unawareness is by definition 'unreportable' on by the person concerned, it is not possible to verify that a denial state is being experienced. This means that for criterion validity to be established, assessment measures need to be compared with some other assessment which can confirm the denial state (e.g. retrospective interviews with those whose unawareness has diminished naturally; O'Callaghan, Powell & Oyebode, 2006).

Given the challenges of assessing denial, it is reasonable to ask how effective are the tools which are designed to assess for the presence of denial. To date, there have been no systematic reviews of the methods used to assess psychological denial in brain-injured participants. However, an initial examination of the relevant literature highlights several relevant issues. Firstly, despite being a relatively sparse literature, there is substantial variation in the methods that have been used to explore denial (including qualitative studies, questionnaires and experimental methods). In order to increase the comparability of any assessment of methodological quality, this review will focus exclusively on questionnaire measures. Secondly, many studies make reference to the possible influence of psychological denial, or cite it as a potential explanation for their results (e.g. Anson & Ponsford, 2006), but since the presence of denial is typically not the primary focus of those studies, it is often not directly measured. Therefore, this review aims to: (1) identify questionnaire measures used to directly assess the presence of denial; and (2) determine whether those measures which do exist accurately measure the presence of denial.

Methodology

Inclusion Criteria

Studies using questionnaires to directly assess the presence of psychological denial following acquired brain injury.

Exclusion Criteria

Studies that sample participants with neurodegenerative or psychiatric disorders or whose participants were not assessed for unawareness were excluded, as were those adopting single-case, qualitative or descriptive designs. Review articles or commentaries and studies published in language other than English were excluded.

Search strategy

The following population search terms:

(HEAD INJURY or BRAIN INJURY or TBI or ABI or STROKE or CVA)

were used in combination with:

(ANOSOGNOSIA) or (DENIAL) or (LACK* ADJ2 INSIGHT) or (IMPAIR* ADJ2 INSIGHT) or
(AWARENESS) or (UNAWARENESS) or (DEFICITS ADJ2 SELF-CONSCIOUSNESS)

Searches were made to the following databases:

MEDLINE

EMBASE

Cochrane Center for Controlled Trials

Cochrane Database of Systematic Reviews

PsychINFO

Nursing Index

Health and Psychosocial Instruments

The following limits were applied to searches:

Population:

1. Adult
2. >18 years

Date: 1990- February 2011

Stage 1:

Using the above search strategy, 1916 abstracts were recovered. All abstracts were read by the main author. Two hundred and sixty-seven papers relevant to the review were retrieved in full-text format.

Stage 2:

Full text articles were read by the main author and those failing to meet inclusion criteria were removed (220), resulting in 47 articles. Studies were then assessed for exclusion criteria, producing twelve articles.

Stage 3:

Remaining articles were searched to identify questionnaire measures used to examine denial. This resulted in eight assessment measures which are detailed below:

1. **Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (MOT-Q;** Chervinsky, Ommaya, deJonge, Spektor, Schwab et al., 1998). This 31-item scale assesses an individual's motivation to engage in rehabilitation, and includes four sub-scales, including one designed to be sensitive to both denial and anosognosia. Participants are asked to read the items and respond on a 0-4 rating scale, indicating their agreement with these statements. Cumulative totals are produced for each of the four scales. Examples of items include, 'There is nothing wrong with me' and 'The head injury has had minimal effect on my abilities'.
2. **Levine Denial of Illness Questionnaire (LDIS;** Levine, Warrenburg, Kerns, Schwartz, Delaney et al., 1987). This 22-item scale is designed to assess psychological denial in physically ill populations. Staff members are asked to make 'yes/ no' responses which are then collated. Examples of items include 'minimisation of illness', 'cheerful mood' and 'exaggerated self-confidence'.
3. **Freiburg Questionnaire on Coping with Illness (FQCI;** Muthny, 1989). This 23-item scale is designed to assess coping styles in German-speaking physically ill populations. The scale assesses patient's beliefs, with three items being specifically designed to explore denial or minimisation of illness.
4. **Clinician's Rating Scale for Evaluating Impaired Self-Awareness and Denial of Disability After Brain Injury (CRS;** Prigatano & Klonoff, 1998). This 20-item scale is designed to assess patients' behaviour over a specified time period. Two 10-item subscales are used to indicate to what extent denial or anosognosia are present. Items were developed from the authors' own

clinical experience regarding those behaviours considered to be indicative of either cause of unawareness. Staff members are asked to make 'yes/ no' responses which are then collated for each subscale. Items include, 'patient shows a negative affective reaction when given feedback that he or she may be more impaired than he or she reports'.

5. **Denial Assessment Tool for Stroke (DATS;** Christensen, Cook & Martin, 1997). This 22-item scale is designed to assess patients' behaviour over a specified time period, indicating to what extent denial or anosognosia are present. Two 11-item subscales are used to indicate the presence of denial and anosognosia. The psychological denial subscale was transposed from the Alcohol Denial Assessment Tool (ADAT; Wing, Hansen & Martin, 1994). Staff members are asked to make 'yes/ no' responses to items which are then collated for each subscale. Examples of target behaviours include Cognitive Defences (minimization of deficits, blaming others) and Behaviour Incongruent with Affect (e.g. 'clowning', seduction or mothering of others).
6. **Marlowe-Crowne Social Desirability Scale (MCSDS;** Crowne & Marlowe, 1960). This 33-item scale is designed to be an implicit measure of denial, assessing socially-desirable responding which has been argued to act as a trait measure of 'defensiveness'. Participants are asked to read the questionnaire and to make 'yes/ no' responses which are collated. The proportion of items 'incorrectly' endorsed is taken to indicate the extent to which that person is engaging in socially desirable responding. Examples of

items include, 'I always try to practice what I preach' and 'I don't find it particularly difficult to get on with loud mouthed, obnoxious people'.

7. **Symptom Expectancy Checklist** (SEC; Mittenberg Di Giuilo, Perrin & Bass, 1992). This 30-item scale is designed to assess symptom endorsement for post-concussion syndrome. Participants are asked to make 'yes/ no' responses to statements and their results are collated. Ownsworth & McFarland (2004) propose that significant disparity between expected and achieved scores is indicative of 'coping-related denial' or presentation management. Examples of items include, 'I forget where my car was parked' and 'I have trouble thinking'.
8. **Emotional Hayling Sentence Completion Task** (Emotional Hayling; Foutopoulou, Pernigo, Maeda, Rudd & Kopelman, 2010). This 30-item scale is designed to be an implicit measure of denial, assessing subjects' completion times for 10 neutral-, negatively-toned and disability-related sentences. Latencies are collated for each sentence type with longer latencies believed to indicate implicit processing of sentence material. This is in contrast to patient's explicit ratings of how relevant each item was to their present situation. Examples of items include *neutral-* ('When your car breaks down you may need to take it to a ____'); *negative-* ('After a severe sexual assault your confidence may be ____'), and *deficit-related* ('A hoist is sometimes used to lift disabled people off the ____').

Assessment of Methodological Quality

Methodological quality was assessed using a modified version of the rating scale by Terwee, Bot, de Boer, van der Windt, Knol et al. (2007) for the assessment of measurement properties of health status questionnaires. This scale was devised in order to compensate for the lack of explicit criteria for what constitutes good measurement (Terwee et al., 2007; pp.32). This measure identifies several psychometric properties which are important when constructing questionnaires for use within a health context, such as criterion validity, internal reliability, inter-rater reliability and responsiveness to change (see table below).

Several modifications were subsequently made to the original scale to increase its utility in the present review: (1) The 'criterion validity' item ['Convincing arguments that gold standard is "gold" AND correlation with gold standard >0.70'] was replaced with a similar item relating specifically to the unawareness context [item 7]; (2) items relating to 'Floor and ceiling effects' ['<15% of the respondents achieved the highest or lowest possible scores'], 'absolute measurement error' ['minimal important change < smallest detectable change OR minimal important change outside limits of agreement'] and 'interpretability' ['mean and standard deviation scores presented of at least four subgroups of patients and minimal important change defined'] were removed from the original scale due to concerns about applicability to all assessment measures; (3) Items were added which assessed whether: (a)

questionnaires conflated unawareness and denial [item 6] ; (b) whether the measures were validated in a neurological sample [item 8] (see below).

A notable problem with Terwee et al.'s criteria is their request for Cronbach's alphas as part of determining construct validity, particularly since this statistic concerns measurement reliability. The present review retained their interpretation of validity for the purposes of comparability, although it is acknowledged that this may artificially reduce the validity scores of measures that did not adequately explore *reliability*.

Table 1: Quality criteria for measurement properties of questionnaires used to assess denial (adapted from Terwee et al., 2007)

<p><u>1. Content validity</u>- The extent to which the domain of interest is comprehensively sampled by the items in the questionnaire</p>	<p>+ A clear description is provided of the measurement aim, the target population, the concepts that are being measured, and the item selection AND target population and (investigators OR experts) were involved in item selection;</p> <p>? A clear description of above-mentioned aspects is lacking OR only target population involved OR doubtful design or method;</p> <p>- No target population involvement;</p> <p>0 No information found on target population involvement.</p>
<p><u>2. Internal consistency</u>- The extent to which items in a (sub) scale are inter-correlated, thus measuring the same construct</p>	<p>+ Factor analyses performed on adequate sample size (7 * # items and >100) AND Cronbach's alpha(s) calculated per dimension AND Cronbach's alpha(s) between 0.70 and 0.95;</p> <p>? No factor analysis OR doubtful design or method;</p> <p>- Cronbach's alpha(s) <0.70 or >0.95, despite adequate design and method</p> <p>0 No information found on internal consistency.</p>
<p><u>3 Construct validity</u>- The extent to which scores on a particular questionnaire relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured</p>	<p>+ Specific hypotheses were formulated AND at least 75% of the results are in accordance with these hypotheses;</p> <p>? Doubtful design or method (e.g. no hypotheses);</p> <p>- Less than 75% of hypotheses were confirmed, despite adequate design and methods;</p> <p>0 No information found on construct validity.</p>
<p><u>4. Reliability</u>- The extent to which patients can be distinguished from each other, despite measurement errors (relative measurement error)</p>	<p>+ ICC or weighted Kappa >0.70;</p> <p>? Doubtful design or method (e.g., time interval not mentioned);</p> <p>- ICC or weighted Kappa <0.70, despite adequate design and method;</p> <p>0 No information found on reliability.</p>

5. <u>Responsiveness</u> - The ability of a questionnaire to detect clinically important changes over time	+ SDC or SDC<MIC OR MIC outside the LOA OR RRO 1.96 OR AUC>0.70; ? Doubtful design or method; - SDC or SDC>MIC OR MIC equals or inside LOA OR RR<1.96 OR AUC <0.70, despite adequate design and methods; 0 No information found on responsiveness.
6. <u>Construct validity</u> - Does the assessment method conflate the measurement of denial with measurement of unawareness?	+ No - Yes
7. <u>Criterion validity</u> - Is independent evidence provided that the person was experiencing psychological denial as opposed to anosognosia at the time?	+ Yes - No
8. <u>Clinical Population</u> - Was the measure validated in an acquired brain injury population?	+ Yes - No

MIC= minimal important change; SDC= smallest detectable change; LOA= limits of ICC= Intraclass correlation; SD= standard deviation; (+) = positive rating; (?) = indeterminate rating; (-) = negative rating; **0** = no information available. Doubtful design = lacking a clear description of the design or methods of the study, sample size smaller than 50 subjects (should be at least 50 in every (subgroup) analysis), or any important methodological weakness in the design or execution of the study.

Results

Table 2: Quality ratings of assessment measures

	<u>Quality Rating Criteria</u>							
<u>Measure</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>
MOT-Q	+	?	?	+	0	-	-	+
LDIS	+	?	+	-	+	-	-	+
FCQI	+	-	0	0	0	-	-	-
CRS	+	0	?	0	0	-	-	+
DATS	?	?	0	?	?	-	-	+
MCSDS	+	?	?	+	0	+	-	-
SEC	?	+	0	+	0	+	-	+
Emotional Hayling	+	0	0	0	0	+	-	+

(+) = positive rating; (?) = indeterminate rating; (-) = negative rating; 0 = no information available

There is substantial variability in the methodological attributes of measures used to assess psychological denial in the context of unawareness (Table 1). However, other factors need to be considered when determining the ‘overall quality’ of a given measure, as the cumulative number of positive and negative ratings may not be the best indicator of quality. In this context, the potential conflation of constructs believed to represent unawareness and denial poses significant problems for the internal consistency of an assessment method. Where this does occur, it is possible that a measure could potentially be more sensitive to a different construct from that intended.

In addition, the absence of some form of criterion validity (e.g. relationship with later self-report/ response to psychological treatment) also makes it difficult to determine whether the questionnaire is in fact assessing denial as opposed to general unawareness. Either factor is important in establishing the presence of denial in the context of unawareness; however, both are probably needed for firmer conclusions to be drawn. Although general methodological quality is important when considering the relative value of measures, these two additional factors pose the greatest threat to the validity of a measure of denial in this context and so they will be weighted more heavily when considering a questionnaire's worth.

The Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (Chervinsky et al., 1998) possesses relatively good methodological quality, including its validation in a large brain-injured sample. However, despite being designed to measure both denial and anosognosia, there is no evidence of two separate factors developing within the broader 'lack of awareness' construct (e.g. Chervinsky et al., 1998). Furthermore, the surface structure of the items could be sensitive to the presence of reports of unawareness, rather than specifically to psychological denial. Finally, there is no indication of the authors relating their measure to later self-report or some other proof that denial was indeed present during the unawareness. Another issue pertains to the scale's relationship with the Minnesota Multiphasic Personality Inventory-2 (MMPI-2). Crowne & Marlowe (1960) argue that defensiveness (a synonym for denial) should be distinct from psychopathology. They believed that their scale's (MCSDS) poor

correlations with the MMPI was a significant strength. Therefore, it remains necessary to ascertain exactly what components of unawareness the MOT-Q is measuring.

The Levine Denial of Illness Scale (Levine et al., 1987) achieved good methodological ratings, although it should be noted that these were derived from patients with coronary heart disease. A later study confirmed the two-factor structure of the scale (Levine et al., 1994), albeit with small numbers of patients post-CVA (n=19). However, as with the MOT-Q this measure suffers from its items potentially being more sensitive to brain injured participants' unawareness rather than denial specifically. Furthermore, the criterion validity of this scale has not been established, something that is particularly important given the challenges faced in when applying it to unaware populations. A final limitation is that it was not possible to examine the original version of the scale, as Levine et al. (1994) provided an incomplete reference. As such, assessment of the scale was based on inferences made from the information provided in Levine et al. (1994).

The Freiburg Questionnaire on Coping with Illness (Muthny, 1989) was developed as a German language coping styles questionnaire. Assessment of methodological quality of the scale as a whole was poor, with shortcomings identified regarding reliability and factor strength. Specifically, Nickel, Wunsch, Egle, Lohse & Otto (2002) found that the internal consistency of the scale was poor, even when problematic items were removed. A further difficulty is that although the studies employing it have been in English, it was not possible to examine an English language version of the scale. This means that

inferences were made from a brief description of the three 'minimisation' items in Hermann et al. (2000). However, even with an English translation available there would be the risk of losing nuances of meaning in the translation.

The Clinician's Rating Scale (Prigatano & Klonoff, 1998) also exhibited weaknesses when assessed for methodological quality. Specifically, difficulties were identified with item development, where items were developed from the authors' observations, but without any evidence that these in fact measured denial. Furthermore, inter-rater agreement on categorisations was derived from only a subset of the initial participant sample, and was only marginally above chance (58%). The lack of criterion validity was accompanied by the potential conflation of items in relation to unawareness and denial.

Shortcomings were evident when the Denial Assessment Tool for Stroke (Christensen et al., 1997) was assessed for methodological quality, with a small sample and inappropriate statistics used to determine the reliability of the sample. As with the CRS, items were developed from the authors' own observations, but without evidence that these in fact measured denial rather than some other behavioural phenotype. Furthermore, some of these behaviours (e.g. minimising; attributing to others) may simply reflect participants' ways of explaining their deficits due to unawareness, rather than denial specifically. These issues notwithstanding, a unique strength of the DATS is that it is the only measure of those examined which has used a prospective design. Christensen et al. (1997) examined the profiles of patients at several time points post-

CVA, noting that denial- and neurologically-related unawareness behaviours varied as time elapsed. While this suggests that the use of denial varies as recovery from the stroke progresses, caution must be observed. Given the issues described earlier with item development, it could mean that observations of a specific set of behaviours increased in reliability over this period, rather than denial per se increasing.

The Marlowe-Crowne Social Desirability Scale (Crowne & Marlowe, 1960) performed favourably on assessment, with good internal consistency and reliability. Denial items are not conflated with the behavioural symptoms of unawareness, although there was no evidence of criterion validity in an unaware sample. However, there remain several issues associated with the use of this measure in a brain-injured population. Firstly, despite its use in brain-injured samples (e.g. Ownsworth & McFarland, 2004; Ownsworth et al., 2004) the MCSDS has not been validated in this patient group. Secondly, it is unclear whether one can infer that, having the propensity to generally respond defensively (e.g. Ramanah & Martin, 1980) a person was engaging in psychological denial at that particular moment in time. The MCSDS was used by Levine et al. (1987) for the purposes of establishing the discriminant validity of the LDIS, and they argued that as a trait measure of defensiveness, it was quite different from the concept of denial exhibited in physically-ill populations. This was supported by later analysis showing it to be uncorrelated with the LDIS in a coronary heart disease sample. This raises questions about what exactly is being measured by the MCSDS, as well as how this relates other conceptualisations of denial or presentation management.

The Symptom Expectancy Checklist (Mittenberg et al., 1992) performs equally favourably with the highest rated measures in terms of general methodological quality and its development in a brain-injured sample provides adequate validity. However, more problematic is its use as a measure of 'coping-related denial' (e.g. Ownsworth & McFarland, 2004). The authors argue that it provides a measure of under-reporting of common everyday problems resulting from head injury, with low-symptom reporting being indicative of subjects minimising their problems. However, this line of reasoning is open to question, as the SEC may simply be an example of a self-report measure of unawareness, where the degree of impairment is inferred by comparing scores with control group responses. This does not mean that this measure lacks value; simply that it is uncertain how it can meaningfully be applied in the context of unawareness.

The Emotional Hayling task (Foutopoulou et al., 2010) performed unfavourably in terms of methodological quality, with untested constructs and limited validation in neurological samples. Nonetheless, it may still represent the basis of a promising method of assessing psychological denial, as the strength of the measure lies less in its overall psychometric properties and more in its discriminant validity. Foutopoulou et al. (2010) found that those with unawareness for hemiplegia were uniquely slowed when completing sentences containing deficit-related material, as compared with neutral or negative emotion-related items. This was in comparison to hemiplegic patients with awareness of their deficits, who were not slow on any items. Importantly, explicit

ratings of how relevant items were to participants were similar for both groups.

Although this measure does not address the issue of criterion validity, its use of an implicit measure avoids the problem of conflating participants' responses to unaware and denial constructs.

Discussion

The above narrative outlines three approaches to measuring denial which have been adopted so far: those inferring denial from participants' beliefs about their deficits; observing behavioural indicators of denial; using implicit measures of denial and defensiveness. In terms of their ability to assess denial in the context of unawareness, these three sets of measures appear to perform quite differently.

On the basis of current research, measures of patients' beliefs about their deficits (SEC; MOT-Q; Freiburg Questionnaire on Coping with Illness) are unlikely to be uniquely assessing denial in this context. In the cases of the MOT-Q and Freiburg, this is likely to do with the manner in which information about denial is obtained. Patients' responses could reflect beliefs about whether they have any deficits (unawareness), rather than measuring any underlying reasons for this being the case (e.g. denial). The SEC is a methodologically sound measure of symptoms following mild head injury, although it is questionable whether it actually assesses 'coping-related denial', since there is no necessary relationship between lower symptom reporting and denial specifically. Most

of these questionnaire measures which have been used to examine denial possess good psychometric properties, and difficulties observed in this specific context should not be taken to imply poor utility in other clinical populations or scenarios.

Behavioural measures (LDIS, CRS and DATS) experience similar methodological difficulties to the previous group of belief measures, particularly in relation to the manner in which items were created, as well as their reliance on unverified behavioural indicators of denial. Specifically, it is not that the behavioural indicators are in themselves problematic, simply that some form of independent evidence is needed to show that they map onto denial rather than unawareness. However, in contrast to the measures of patients' beliefs discussed above, later research has provided some evidence of construct validity, or responsiveness of denial items to change over time for behavioural measures (e.g. Kortte, Wegener & Chwalisz, 2003; Christensen et al., 1997). This suggests that something relating to unawareness and denial is being measured, although it is unclear what exactly this is.

Implicit measures (MCSDS and Emotional Hayling) represent the most methodologically robust attempts to assess denial in the context of unawareness. Their greatest strength is that because they assess underlying constructs rather than behavioural phenomena, they are unlikely to conflate denial with patients' unaware states. The psychometric properties of the measures vary significantly, as do the implications of this on their utility. The MCSDS is the most psychometrically robust, which is particularly important

given that it is a self-report questionnaire. The Emotional Hayling is less psychometrically sound than the MCSDS, although its format lessens any negative impact of this in terms of sensitivity and value.

This review highlights several methodological issues which need to be addressed by future research. Firstly, there is a need to assess the construct validity of assessment measures in unaware neurological samples, particularly regarding the extent to which measures supposedly assessing the same theoretical constructs (i.e. denial) are related. Preliminary evidence exists (e.g. Ownsworth, McFarland & Young, 2002; Levine et al., 1987) although this needs to be examined thoroughly in this unique context. Criterion validity should also be explored, either by comparing responses on questionnaires with later self-reports (e.g. O'Callaghan et al., 2006), or following psychological therapy designed to reduce denial (e.g. Motivational Interviewing).

There is also a need for prospective designs in this area of research, particularly given that unawareness is a phenomenon known to change over time (Jehkonen, Ahonem, Dastidar, Laippala & Vilkki, 2000). Denial may conceivably coexist with anosognosia and contribute to a person's overall state of unawareness (Prigatano & Klonoff, 1998), with the balance differing from person to person (e.g. Foutopoulou et al., 2010) as well as over time (e.g. Christensen et al., 1997). Furthermore, prospective designs would also address an issue that was absent from almost all measures, namely a lack of data on the responsiveness of numerous measures to clinically significant change.

However, this raises the question of why these methodological issues have not already been addressed if they are of such importance to this area of research. One possible explanation is that increasing criticism of the ethics and validity of using psychoanalytic concepts has reduced the volume of research in this area (e.g. Crombez et al., 2009). This may in part represent a shift away from Freudian concepts that are frequently considered to be poorly defined or operationalised, combined with the increasing dominance of cognitive theory within clinical psychology. Recent theoretical and experimental work which has successfully explored psychodynamic theory (e.g. Fonagy & Target, 2006; Turnbull et al., 2002) has made significant efforts to operationalise concepts and to test the hypothesised neurocognitive processes. Alternatively, it could be that the methodological changes suggested in this review present practical barriers that are disproportionate to any benefits that could be derived from overcoming them. For example, in order to produce a subset of patients whose unawareness has receded (as would be needed to overcome problems of criterion validity), very large initial samples of unaware patients would likely be required. Would this investment of resources represent value for money and produce clinically meaningful results?

A final issue relates to the ethics of examining denial in those with acquired brain injury. Assessing for the presence of denial may allow rehabilitation staff to tailor treatments to a patient's unique needs. However, there is also the risk that ill-considered use of an assessment measure could result in denial becoming a diagnostic label given to a

patient. There is a concern that this may have a negative influence on the care which they receive, and that the label will remain with them long after it has become relevant or appropriate. The issue of inappropriate use of assessment measures is not unique to denial of deficits, and has long been a topic of discussion in neuropsychology (see Gottfredson & Saklofske, 2009 for a discussion of intelligence testing), and this issue remains important regardless of whether assessment measures of denial are actually valid. Staff and relative behaviour can be affected by the outcome of an assessment, irrespective of the validity of that process.

As such, any attempt to assess denial needs to be informed by the principles of clinical neuropsychology (e.g. Cubelli & Della Sala, 2011). Specifically, it should be driven by a clear clinical purpose, and conducted in the context of present theoretical understanding of the aetiology, nature and course of unawareness (e.g. Marcel, Tegner & Nimmo-Smith., 2004). Importantly, it should be considered only the beginning of a broader formulation of psychological status or function, and as with any formulation, must be open to revision in light of new information. Thus while this review does not advocate restricting the assessment of denial, it does recommend giving serious consideration to the clinical and social implications of carrying it out.

Conclusion

This review has drawn together those assessment measures used to assess denial in the context of acquired brain injury. These measures vary substantially in methodological quality, as well as in the probability that they measure denial in the context of unawareness. On the basis of this review, the most promising measures of denial in brain injury are the Emotional Hayling and Marlowe-Crowne Social Desirability Scale, due to their avoidance of conflating the behavioural responses of unawareness and denial. However, there are a number of methodological issues associated with both scales, including lack of adequate validation in brain-injured samples and unproven criterion validity. On the basis of current research, it is argued that the other assessment measures' conflation of unawareness and denial means that they lack meaningful validity when assessing denial. The clinical and ethical implications associated with this should preclude their use until further research is conducted.

Denial following brain-injury will continue to be a difficult area in which to conduct research. The most practical method of addressing these difficulties entails establishing the convergent validity of those assessment measures currently employed (e.g. MCSDS, Emotional Hayling; LDIS; CRS; DATS). The second entails establishing criterion validity by means of retrospective reviews with participants whose unawareness has reduced. More generally there is a need for research to move beyond the simplistic understanding of this phenomenon attributed to Weinstein & Kahn (1955) and engage

with modern understandings of denial (e.g. Foutopoulou et al., 2010; Miller & Rollnick, 2002). Specifically, this means utilising qualitative and experimental designs to explore how denial may manifest in those with acquired brain injury and how these relate to current assessment measures.

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Chapter 2: Major Research Project

Rehabilitation of executive function deficits following acquired brain injury: a randomised controlled trial using Goal Management Training and Implementation Intentions to improve prospective memory.

Andrew Wood* & Jonathan Evans

Academic Unit for Mental Health & Wellbeing

Keywords:

Neuropsychological Rehabilitation; Implementation Intentions; Executive Function; RCT; Prospective memory

*** Correspondence to:**

Andrew Wood
Academic Unit for Mental Health & Wellbeing
Academic Centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Lay Summary

Brain injury is often associated with difficulties in dealing with novel, poorly-structured or complex problems. A common problem occurs with an ability called 'prospective memory' (PM). PM is an important faculty that enables us to put our plans into action at a later time. PM is particularly susceptible to the effects of brain injury, because it requires a number of different mental processes for it to work properly. This study attempts to improve impaired PM performance in those with brain injury using a training technique called 'Implementation Intentions', which encourage participants to use imagery. They aim to set up strong associations between a particular behaviour, and a cue that signals when it is time for them to act. To assess the effectiveness of this intervention, brain-injured participants were randomly placed into two groups. Both groups received a brief intervention to improve problem-solving and planning skills (Goal Management Training). Participants then received either implementation intentions training (experimental group), or an imagery training exercise that wasn't expected to work (control group). The results showed that there was no meaningful difference between the treatments, and that those receiving the control intervention improved just as much as those receiving the implementation intentions training. This may be due to several factors, including the abilities of participants in each group, the intensity and duration of training, or the way in which participants were assessed.

Abstract

Introduction: Deficits in executive function (e.g. planning, problem-solving, prospective memory) following brain injury are associated with significant negative social and occupational outcomes. Prospective memory (PM) is particularly susceptible to the effects of brain injury, as it relies on controlled attentional resources to establish and recall intentions. Implementation intentions (II) have been shown to improve performance on prospective memory tasks across a variety of durations, by circumventing controlled attention and establishing strong cue-action associations using imagery and declarative statements.

Aims: To determine the efficacy of a theory-based training intervention for prospective memory deficits following acquired brain injury.

Methods: A single-blind, randomised trial was used to assess the efficacy of implementation intentions as compared to a control intervention for individuals with acquired brain injury. A within-between repeated measures designs was used. Participants were assessed using an ecologically valid measure of executive function.

Results: No significant differences in interaction effects were found according to treatment allocation. Use of baseline performance, estimated premorbid intelligence, depression, fluid intelligence and processing speed as covariates did not result in significant changes to the effectiveness of interventions.

Discussion: The lack of treatment effect may be attributable to several factors, including the interaction of severity of impairments, length of training, and complexity of the

outcome measure. The appropriateness of group designs when assessing neuropsychological rehabilitation is also discussed.

Introduction

Executive function refers to the higher-order processing of internally- and externally-generated stimuli (Burgess, Dumontheil & Gilbert, 2007), and includes abilities such as planning, concept formation, impulse control, metacognition and self-monitoring.

Deficits in executive function have been associated with significant impairment in everyday functioning, leading to poor vocational and social outcomes (Mazauk, Masson, Levin, Alaoui, Mauretta et al., 1997). Executive deficits have historically been conceptualised as a largely homogenous syndrome, such as 'frontal lobe syndrome', and most recently 'dysexecutive syndrome' (Burgess et al., 2006). However, recent investigations have questioned the validity of this syndromal perspective (e.g. Stuss & Alexander, 2007), with more comprehensive models acknowledging the separation of function within a broader attentional system.

In their influential model of executive function, Shallice & Burgess (1996) delineate the processes involved in the executive system used for complex everyday tasks. They propose that in response to a given situation, individuals construct temporary new schemas (behavioural templates or protocols used to achieve a goal). This can occur spontaneously, or through a process of problem solving (an iterative cycle involving problem formation, deepening of the solving attempt, and establishment of a 'success criterion' against which later solution attempts are compared). Once developed, schema are implemented in accordance with 'contention scheduling' (the process of choosing

between well-established action sequences and thought processes; Burgess et al., 2007). However, to function efficiently in real-world tasks, two special purpose processes are used. Firstly, to reduce the cognitive load associated with constructing new schema, an episodic/ autobiographical memory system is used to provide similar experiences when confronted with novel situations and problems. Secondly, where schema are not to be implemented immediately, a prospective memory (PM) component assists in creating and realizing the schema later.

This prospective memory component appears to be particularly susceptible to the effects of brain injury, with deficits frequently appearing following injury (e.g. Shum, Valentine & Cutmore, 1999). Failures in prospective memory are both familiar and important, as they range from the benign but irritating (forgetting to post a letter or meet a friend), to the potentially disastrous (leaving pots burning on the stove). Shallice & Burgess (1991) argue that having identified a 'to-be-remembered' task, a person creates an 'intention marker', a neural trigger represented within a three-dimensional cognitive space. When a person's conscious attention later encounters an intention marker, it brings the intention into awareness again and inhibits current ongoing activity. It is argued that failure of prospective memory is frequently a result of 'goal neglect' (Duncan, Emslie, Williams, Johnson & Fraser, 1996) or 'strategy application disorder' (Shallice & Burgess, 1991). While these two deficits give rise to subtly differing patterns of behaviour, they both result in the failure to carry out appropriate activities

given a relevant intentional cue. Importantly, this is in spite of accurate verbal recall of the intention to be carried out.

There are two forms of prospective memory tasks: time-based (remembering to do something at a particular time e.g. cooking, meeting a friend), and event-based (remembering to do something on the occurrence of a specific prompt, such as passing a message onto a friend when you see him/her). It has been argued that time-based prospective tasks provoke a considerably greater cognitive load than event-based remembering, particularly given the absence of environmental cues to provoke recall (Einstein, McDaniel, Thomas, Mayfield, Shank et al., 2005; Kvavilashvili & Fisher, 2007). Factors that have been shown to influence event-based recall include cue salience, relevance, the propositional structure of intentions and the strength of cue-intention association (e.g. McDaniel & Einstein, 2000; McDaniel, Guynn, Einstein & Breneiser, 2004).

Explanations for time-based prospective memory have received significantly less attention (Kvalilashvili & Fisher, 2007), with the competing models being the test-wait-test-exit model (TWTE) and random-walk model (Harris & Wilkins, 1982; Wilkins 1979). TWTE argues that successful performance is dependent on the monitoring of time, possibly using an internal clock, accompanied by occasional checks that increase in a J-shaped curve towards the target time. Alternatively, according to the random-walk

model of prospective memory, the intention sits within a multidimensional representation of consciousness, triggered only when the person's attention accidentally stumbles upon it or upon closely related concepts within the internal or external environment (e.g. events or concepts relating to *time*). As compared to the TWTE model, the random-walk model implies that few- if any- attentional resources are required to trigger a time-based intention.

A number of interventions have attempted to rehabilitate deficits in prospective memory; however, in considering them, an important distinction must be made between rehabilitation approaches aiming to compensate for deficits (by providing neurological and/or environmental support for a deficit), and those that seek to ameliorate lost abilities through training (Evans, 2006). Manly, Hawkins, Evans, Woldt & Robertson (2001) and Fish, Evans, Nimmo, Martin, Kersel et al. (2007) adopt the former approach, using intermittent prompts to cue prospective memory tasks in patients with traumatic brain injury. They found that even when prompts were semi-random, and were non-contingent with the cue, they nonetheless produced significant improvements in performance compared with controls. Manly et al. (2001) argue that the prompt provides external support for intentional markers that are competing for expression, orienting attention away from the immediate task. This explanation is consistent with Burgess et al. (2007) 'gateway hypothesis' of attentional control, which argues that aspects of lateral and medial rostral Brodmann Area 10 are responsible for mediating

between stimulus-oriented and stimulus-independent cognition; essentially the switching of attention between the outside environment and one's internal goals.

Remedial or training-based interventions for PM deficits can be divided into those looking at Goal Management Training (Robertson, 1996) and those looking at Implementation Intentions (Gollwitzer, 1999). Levine, Robertson, Claire, Carter, Hong et al. (2000) randomised participants with brain injury to either Goal Management Training (GMT) or Motor Skills Training (MST), and assessed their performance on a proof reading task (participants were to circle numbers, underline fruits and vegetables, and put an 'X' through liquids). They found that those assigned to GMT were significantly slower and more accurate than the MST group, taken to indicate the greater application of care and attention to the task in hand. However, other studies have provided equivocal support for the use of GMT in prospective memory. For example, Brown & Evans (in preparation) assessed PM performance on a virtual reality task following brief GMT training and using auditory alerts, with the treatment group showing improvement on a measure of event-based PM. There was no overall improvement on other measures of time- and event-based PM (although this may be due to ceiling effects on the task performance).

There are, however, important qualitative differences between the tasks used in these studies, and the null findings may reflect incompatibility between GMT and specific PM tasks rather than the absence of potential effect. For example, the proof-reading task

used by Levine et al. (2000) is a highly structured PM task, akin to those used in experimental investigations of PM. It is possible that given a task where an individual is engaged in spotting stimuli (with few- if any- external distractions or competing tasks), the intention remains in conscious attention throughout. However, when an intention is to be activated while the individual simultaneously performs other demanding tasks (e.g. Brown & Evans, in preparation), GMT may not in itself provide sufficient assistance, even with auditory alerts to remind them of their training and their intention. Nonetheless, GMT is likely to be a critical part of the process, as it supports the development of clear planning.

In contrast, implementation intentions (II) are explicit statements about a person's intentions when they detect a particular cue (e.g. 'when I see X, I will do Y'), and includes the use of imagery to create a rich mental representation of possible stimuli which may also occur with the cue. Implementation intentions are believed to work, not only because they establish a strong cue-response association, but also because they circumvent the need for controlled attention to realize the intention. Importantly, II have been shown to be effective in both event- and time-based PM tasks. For example, Prestwich, Conner, Lawton, Bailey, Litman et al. (2005) used II to promote breast self-examination, and found that a statement linking the specific intention and a commitment to self-examining in the next month was found to increase both the likelihood and frequency of self-examination at one- and six-month follow-up. Similarly, Liu & Park (2004) looked at the effect of II on accuracy of blood glucose checking in

older adults, and found that those using II performed tests nearly 50% more often than controls over a period of three weeks. This study also suggests that II may work even where there are no inherent motivators, as none of the participants had diabetes.

Using a neurologically impaired sample, Kardiasmenos, Clawson, Wilken & Wallin (2008) allocated patients with Multiple Sclerosis to either II or control conditions, following which they were then tested on a board game intended to simulate the prospective memory requirements of everyday life. They found a significant difference between the MS intervention and control groups, with the intervention group showing a greater proportion of correct event-based PM responses in the task. Lengfelder & Gollwitzer (2001) found that II had a significant effect in improving dual-tasking performance in those with frontal brain injury. Unfortunately, the practical implications of this study are unclear, as the study did not explore the impact of II on functional or ecologically valid measures.

Consequently, there is a need to explore further the impact which II have on PM performance in those with brain injury. This study aimed to expand on the work of Lengfelder & Gollwitzer (2001), exploring the impact of implementation intentions in those with acquired brain injury, but using ecologically valid outcome measures.

Aims and hypotheses:

This study aimed to:

- Determine the efficacy of a theory-based training intervention for prospective memory.

Hypotheses

1. Participants receiving combined GMT and implementation intention training will perform significantly better on primary outcome measures of prospective memory and executive function than those allocated to combined GMT and control intervention.
2. Participants receiving combined GMT and implementation intention training will perform significantly better on secondary measures of planning and prospective memory (Removals Task) than those allocated to combined GMT and control intervention

Methodology

Design

A single-blind, randomised within-between group design was used. The between-subjects factor was *intervention* (GMT+ Implementation Intentions vs. GMT+ control

imagery intervention), and the within-subjects factor was *time* (baseline and post-treatment).

Participants

Recruitment sources

Participants were recruited and tested between December 2010 and June 2011 from health service and charitable organisations for people with brain injury in Ayrshire, Glasgow, Falkirk and Edinburgh. Participants were tested at the locations they were recruited from, and at the Community Treatment Centre for Brain Injury (Gorbals, Glasgow) and the Sackler Institute for Psychobiological Research (Southern General Hospital, Glasgow).

Inclusion Criteria

Inclusion criteria for the present study were adults with acquired brain injury, aged between 18 and 65 who demonstrated significant impairments in executive functioning. This was defined as scores of less than 9 on the JAAM Prospective Memory subscale.

Exclusion criteria

Participants were excluded if they were less than 6 months post-injury, had a diagnosed premorbid learning disability, were experiencing concurrent severe mental illness, or were currently abusing drugs or alcohol, . Those suffering from a degenerative

neurological disorder, had severe dyslexia or visual impairments, or who were unable to provide informed consent (Adults with Incapacity (Scotland) 2000 Act) to participate in research were also excluded. Due to the nature of the testing materials, those who spoke English as a second language were excluded.

Twenty-one participants with acquired brain injury (ABI) were recruited (see below):

Calculation of sample size

The planned analysis for this study was ANOVA, with one between subjects variable (group) and one within subjects repeated measure (time - assessment occasion).

GPower (v 3.1.2) (Faul et al., 2009) was used to estimate sample size required to detect whether the intervention group had improved more than the control group, reflected in a significant group x time interaction term in the ANOVA. The effect size estimate used in this analysis was based on the effect size obtained in the study of Kardiasmenos et al. (2008). Adopting an implementation intention intervention, they used a neurologically-impaired sample and a functionally-relevant outcome measure of PM. Their analysis achieved a very large effect size ($\eta^2 = 0.227$) across the group x time interaction effect in a repeated-measures ANOVA.

For the present study, which uses a less directive training than Kardiasmenos et al., a more conservative approach was taken, using a medium-large effect size ($\eta^2 = 0.109$; Cohen's $f = 0.35$), with $\alpha = 0.05$. With these parameters, 20 participants would be

required in total to achieve power of 0.8. It was therefore decided that to be even more cautious and aim to recruit 26 participants.

Ethics

Ethical approval for NHS and non-NHS sites was obtained from the West of Scotland Research Ethics Service (WoSRES). Research and Development approval for NHS sites was obtained from NHS Greater Glasgow & Clyde and NHS Ayrshire & Arran. Separate approval was obtained from respective non-NHS sites

Measures

Demographic (age, gender, education and socio-economic status) and clinical (nature of injury, time since injury; estimated post-traumatic amnesia and GCS) information was collected during telephone screening. Socio-economic status was determined using the Scottish Index of Multiple Deprivation (SIMD) system according to participants' postcode.

The following baseline measures were used to characterise the sample: *Adapted Dysexecutive Questionnaire* (DEX; Chaytor, Schmitter-Edgecombe & Burr, 2006); *Prospective and Retrospective Memory Questionnaire* (PRMQ; Crawford, Smith, Maylor, Della Sala & Logie, 2003); Goal Management Questionnaire (GMQ; Manly, Robertson & Levine, personal communication); *Wechsler Test of Adult Reading* (WTAR; The Psychological Corporation, 2001); *Rey Complex Figure Test (Immediate and Delayed)*

(Meyers & Meyers, 1985); *Logical memory (Immediate and Delayed)* subtests of Wechsler Memory Scale (WMS-III); *Symbol-digit Modalities Test* (Smith, 1968); *Matrix Reasoning* subtest from Wechsler Adult Intelligence Scale (WAIS-III; Wechsler, 1997); *Hospital Anxiety and Depression Scale* (HADS; Zigmond & Snaith, 1989); *Tower Test* (D-KEFS, Delis-Kaplan Executive Function System; Delis, Kaplan & Kramer, 2001); *Cambridge Prospective Memory Test* (CAMPROMPT; Wilson, Emslie, Foley, Shiel, Hawkins et al. 2005).

Primary outcome measures

The following measures were used to assess the efficacy of the intervention:

- JAAM Virtual Reality test (Jansari, Agnew, Akesson & Murphy, 2004) was used to assess pre- and post- intervention functioning. The JAAM is a computer-based task which requires participants to complete PM tasks, such as responding to memos, within a virtual office environment. This task has good ecological face validity, requiring participants to respond to ill-defined problems. Participants receive separate scores for planning and PM components, which contribute to a total measure of executive function. Separate scores are given for planning and prospective memory, with the latter divided into three types of tasks: action-, event- and time-based tasks.

- Removals Task (Third Dimension, 2005) was used post-intervention to assess for generalisation of strategies. This is a computer-based task which requires participants to remove items of furniture from a house, while completing certain PM tasks (e.g. remembering to close doors, checking the front door after a set period). Participants are given a score for the efficiency of the strategy that they adopt, errors that they make during this process, and different measures of prospective memory. Due to ceiling effects observed in Brown & Evans (in preparation) a modified version with auditory distraction was used.

Procedure

Potential participants were identified by staff at recruitment sites using screening forms. Written information about the study was provided to potential participants, asking them to contact the researchers if they were interested. Individuals who expressed interest but did not contact the researcher were provided with a reminder letter at their next routine clinical contact; however, further prompting was not pursued beyond this point. Contact details were provided to researchers either directly by the participant, or via a designated member of their care team. Potential participants were screened for eligibility via telephone and those meeting inclusion criteria were included in the study. Questionnaires (Patient and carer PRMQ, Carer DEX & Patient and Carer GMQ) were then posted out to participants for completion 1-2 weeks prior to their appointment. Appointments were arranged via telephone and were followed-up with a letter; an offer was made to participants for a telephone reminder 24 hours before testing sessions.

They were asked to bring to the completed questionnaire to first appointment; those who did not were asked to complete them during the first appointment. Participants attended three separate sessions at approved locations (see above). The first two sessions lasted approximately 2- 2 ½ hours each, and involved completing background neuropsychological tests as well as specific measures of executive function. The third session lasted approximately 2 ½ - 3 hours and involved a training intervention and further neuropsychological testing (see above). Participants were debriefed following the third session and told of their group allocation. Adaptations were made for individuals with motor or sensory impairments, and breaks were provided throughout testing.

Randomisation and blinding

Randomisation to intervention was carried out 1-month prior to testing by a researcher unconnected with the study. Randomisation took place using a random number generator and was blocked to ensure an equal number of participants were allocated to each group. Participants' allocations were concealed in envelopes in testing files, and were only opened by the researcher immediately before the intervention session. This study was single blinded, in that those carrying out the intervention, assessing participants and marking responses were aware of participant allocation, but the participants themselves were not made aware of their allocation until the completion of the post-intervention assessment.

Interventions

Brief Goal Management Training (see Levine et al., 2000) was undertaken initially with all participants to assist with the ability to form intentions. Participants were asked to: Stop; Ask “What is my goal”; List the steps; and Learn the Steps. They were given real-world examples to use to practice these stages. This phase of training lasted approximately 15 minutes and occurred prior to both the experimental and control imagery interventions; in total, training took 45- 60 minutes.

Experimental Intervention

The experimental intervention focussed on the specific components of Implementation Intentions as well as on those influencing the successful recall of prospective cues: (1) Intention formation- this includes the use of imagery and errorless learning strategies to learn associations between target cues and desired actions (for example, visualising themselves immediately performing the action when they see the cue); (2) Event-based PM recall strategies (for example, manipulating the salience of the cue in terms of size, appearance and salience; (3) Time-based PM recall strategies (for example, using imagery to increase associations between cues and time-based objects and concepts (see Appendix 2 for a detailed description).

Control Intervention

The control intervention faithfully employed GMT techniques and terminology, but used a non-specific imagery training exercise adopted by Evans, Wilson, Schuri, Andrade, Baddeley et al. (2000). This involved using imagery to draw the first letter of the cue onto the face of a person that they know well. While this has been shown to improve name recall in amnesic patients, it was not expected to improve prospective memory (see Appendix 2).

Participants were presented with sheets of laminated paper containing the individual learning points of the interventions. Training took place using errorless learning with increasing cues, and participants were provided with prompts and examples throughout this process to assist with learning the strategies. To assist with generalisation, a variety of training tasks were used, including well- and poorly-structured problems, as well as a naturalistic divided attention task.

Statistical methods

Boxplot graphs and the Kolmogorov-Smirnov test were used to assess normal distribution of the data. Descriptive statistics were obtained for demographic and clinical information. Independent sample t- and Mann-Whitney non-parametric test were applied to neuropsychological measures to explore differences between the

groups. A 2x2 repeated-measures ANOVA was applied to the JAAM primary outcome measures to assess group differences over time.

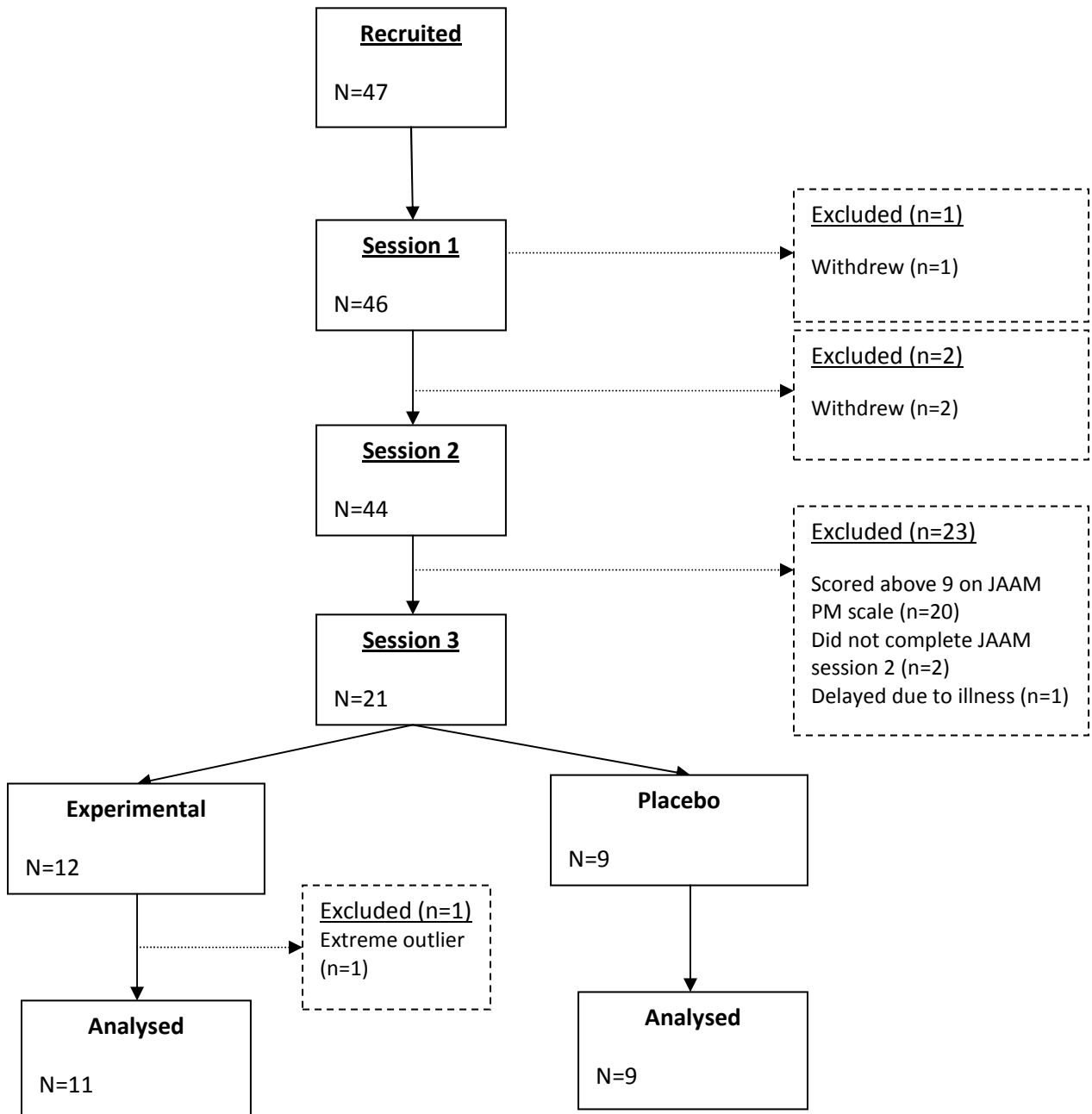
Results

Table 1: Demographic information of sample (n=20)

	Mean/Median (SD)
Gender- Male (%)	71.4%
Age (years)	48.5 (9.99)
Education (years)	13.10 (3.17)
Handedness- Right (%)	95.2%
Time since injury (months)	93.6 (100.81)
Estimated post-traumatic amnesia (months)	49.00 (51.77)

Two-way independent sample t-tests were applied to parametric clinical and demographic data (see table 2). There were no significant differences observed between the groups according to Age ($t(18) = 0.356$, $p=0.726$), Years in Education ($t(18) = -0.241$, $p=0.812$), Duration of Post-traumatic amnesia ($t(18) = 1.451$, $p=0.164$), HADS Anxiety scores ($t(18) = 0.877$, $p=0.392$), Matrix Reasoning scaled score ($t(18) = 0.155$, $p=0.879$), Logical Memory Delayed scaled scores ($t(18) = -1.879$, $p=0.077$), Trail-Making Test A ($t(18) = 1.007$, $p=0.327$), and WTAR Estimated premorbid IQ scores ($t(18) = -0.160$, $p=0.127$).

Figure 1: Flow Diagram of participant recruitment and allocation



Significant group differences were observed on HADS Depression scores ($t(18) = 2.043$, $p = 0.056$), Logical Memory Delayed scaled scores ($t(18) = -2.133$, $p = 0.047$), SDMT scores ($t(18) = -2.654$, $p = 0.016$), Self-rated PRMQ Total scores ($t(18) = 3.06$, $p = 0.007$), Self-rated

PRMQ Prospective memory scores ($t(18) = 2.892, p=0.01$), Self-rated PRMQ Retrospective Memory scores ($t(18) = 3.099, p=0.006$), Other-rated PRMQ Total Scores ($t(18) = 3.06, p=0.013$), Other-rated PRMQ Prospective Memory scores ($t(18) = 2.820, p=0.011$), and Other-rated PRMQ Retrospective Memory scores ($t(18) = 2.541, p=0.02$).

Table 2: Demographic and clinical information of intervention groups

	Intervention (n=11)	Control (n=9)	Statistical
	Mean/Median (SD)	Mean/Median (SD)	significance
Gender- Male (%)	81.8%	60%	n/s
Gender- Female (%)	18.2%	40%	n/s
Age (years)	46.9 (9.62)	49.8 (10.62)	n/s
Education (years)	13.09 (2.11)	13.10 (4.17)	n/s
Handedness (R)	90.9%	100%	n/s
Time since injury (months)	101.82 (116.18)	82.60 (86.08)	n/s
Estimated PTA (months)	63.5 (66.70)	29.89 (20.53)	n/s
Injury type (TBI, CVA, Haemorrhage)	8, 1, 2	7, 0, 3	-
Psychiatric diagnosis (%)	18.1%	10%	n/s
HADS- Depression (/21)	9.73 (4.17)	6.11 (3.62)	$p<0.05$
HADS- Anxiety (/21)	11.09 (5.32)	9.00 (5.29)	n/s

	Intervention (n=11)	Control (n=9)	Statistical
	Mean/Median (SD)	Mean/Median (SD)	significance
HADS- Depression (/21)	9.73 (4.17)	6.11 (3.62)	p<0.05
HADS- Anxiety (/21)	11.09 (5.32)	9.00 (5.29)	n/s
PRMQ- Prospective (Patient)	30.73 (6.39)	22.11 (6.92)	p<0.05
PRMQ-Retrospective (Patient)	30.09 (5.79)	20.89 (7.51)	p<0.05
PRMQ- Total (Patient)	60.82 (12.02)	43.00 (14.07)	p<0.05
PRMQ- Prospective (Other)	30.18 (7.57)	21.78 (5.22)	p<0.05
PRMQ- Retrospective (Other)	27.45 (7.63)	20.56 (3.05)	p<0.05
PRMQ- Total (Other)	57.64 (14.99)	42.33 (8.00)	p<0.05
Rey (Immediate)	30.55 (18.16)	38.7 (13.97)	n/s
Rey (Delayed)	28.46 (14.83)	34.00 (43.80)	n/s
Matrix Reasoning	9.82 (1.78)	9.67 (2.51)	n/s
Logical Memory- I	6.55 (2.66)	9.22 (2.95)	p<0.05
Logical Memory- II	6.36 (3.26)	9.33 (3.81)	n/s
SDMT (z-score)	-2.82 (0.90)	-1.67 (1.03)	p<0.05
Estimated IQ (WTAR)	93.18 (10.72)	102.44 (15.16)	n/s
Trails- A (secs)	59.27 (23.00)	50.33 (14.74)	n/s
Trails- B (secs)	147.91 (94.69)	132.50 (82.90)	n/s

Non-parametric statistics (Mann-Whitney) were applied to data which was not normally distributed. There were no significant differences observed between the groups according to Time since Injury, Rey Complex Figure Immediate Recall, Rey Complex Figure Delayed Recall, Trail Making Test B, and Tower Test Total Achievement Score.

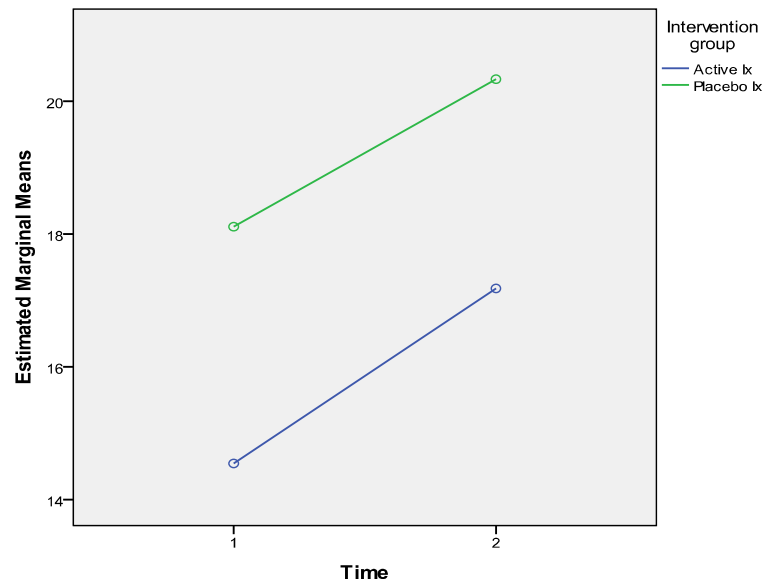
Two-way repeated measures ANOVAs were applied to the primary outcome measures to assess for treatment effects according to intervention group. Sphericity was assessed using Mauchly's test, with this assumption found to be violated for all JAAM variables. In view of this, as well as the small sample size in the present study, lower-bound corrections were applied to analyses. There was a significant main effect for JAAM Total Score for time ($f(1,18) = 10.21$, $p = 0.005$, $\mu^2 = 0.362$), but not intervention group ($f(1,18) = 2.65$, $p = 0.121$, $\mu^2 = 0.128$), and there was no interaction effect ($f(1,18) = 0.74$, $p = 0.788$, $\mu^2 = 0.004$). There were no significant main effects for JAAM Planning Score for time ($f(1,18) = 0.16$, $p = 0.69$, $\mu^2 = 0.09$) and intervention group ($f(1,18) = 0.53$, $p = 0.48$, $\mu^2 = 0.29$), and no interaction effect ($f(1,18) = 0.16$, $p = 0.69$, $\mu^2 = 0.09$). There was a significant main effect for JAAM Prospective Memory Score for time ($f(1,18) = 8.93$, $p = 0.008$, $\mu^2 = 0.33$), and intervention group ($f(1,18) = 4.65$, $p = 0.045$, $\mu^2 = 0.205$), but no interaction effect ($f(1,18) = 0.28$, $p = 0.602$, $\mu^2 = 0.015$).

Table 3- Mean scores for JAAM outcome measure according to intervention group.

		Time 1	Time 2
		Mean/ Median (SD)	Mean/ Median (SD)
JAAM Total	GMT + II	14.55 (4.61)	17.18 (4.67)
	Time-controlled	18.11 (4.94)	20.33 (5.43)
JAAM Planning	GMT + II	6.00 (1.61)	6.00 (1.18)
	Time-controlled	6.56 (1.13)	6.33 (1.94)
JAAM Prospective Memory	GMT + II	3.27 (2.24)	5.18 (2.23)
	Time-controlled	5.56 (1.94)	6.89 (3.06)

Post-hoc power analysis indicated that the present study was underpowered to detect an effect on the interaction of JAAM Total (0.058), Planning (0.067) and Prospective Memory scores (0.79).

Figure 2- Graph of change in Total JAAM score according to intervention group.

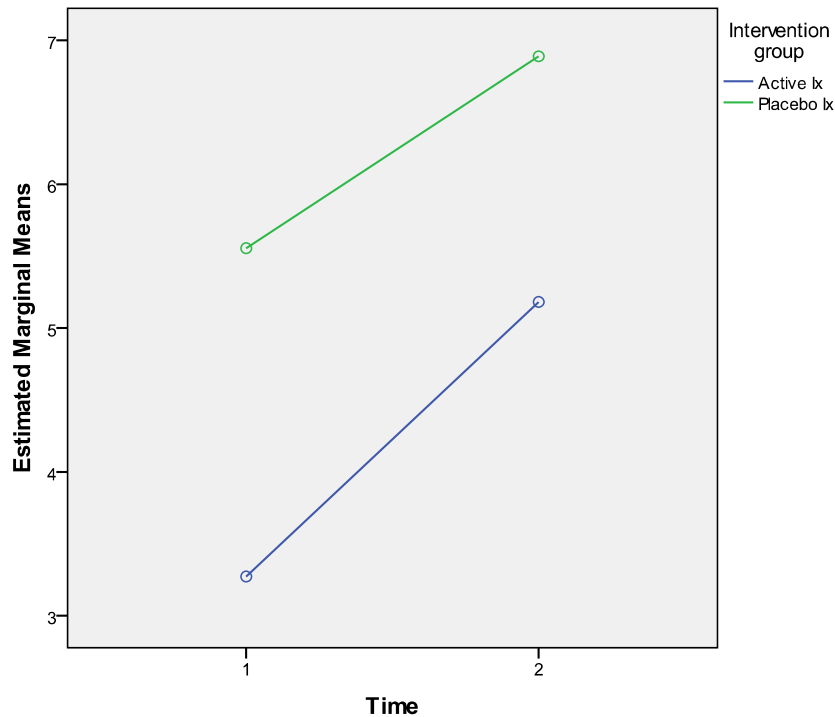


Additional analysis was carried out on the separate action-, event- and time-based Prospective Memory measures. There were no significant main effects for Action-based PM scores for time ($f(1,18) = 0.36$, $p=0.852$, $\mu^2=0.002$), intervention group ($f(1,18) = 3.473$, $p=0.079$, $\mu^2=0.162$), or interaction ($f(1,18) = 0.36$, $p=0.852$, $\mu^2=0.002$). There was a significant main effect for Event-based PM scores for time ($f(1,18) = 10.581$, $p=0.004$, $\mu^2=0.370$), but not group intervention ($f(1,18) = 0.397$, $p=0.536$, $\mu^2=0.022$) or interaction ($f(1,18) = 0.25$, $p=0.623$, $\mu^2=0.014$). There was a significant main effect for Time-based PM scores for time ($f(1,18) = 8.839$, $p=0.008$, $\mu^2=0.329$) and group intervention ($f(1,18) = 5.479$, $p=0.31$, $\mu^2=0.233$), but no interaction effect ($f(1,18) = 0.354$, $p=0.559$, $\mu^2=0.019$).

Removal's Task scores were analysed using independent samples tests (Mann-Whitney and Student's t-test). The results indicate that there were no significant differences

between the groups on Strategy Score ($t(17) = 0.497$, $p = 0.622$) and rule following (Intrusion 1, $p < 0.05$; Intrusion 2, $p < 0.05$).

Figure 3- Graph of change in JAAM Prospective Memory subscale score according to intervention group.



In view of the significant group differences on various clinical tests and baseline JAAM performance (i.e. HADS Depression, Logical Memory Delayed, SDMT; Trail-Making Test B, and PRMQ questionnaire scores), these variables were included as covariates in further repeated-measures ANOVAs. However, their inclusion did not alter the conclusion regarding the effectiveness of the intervention.

Discussion

This study sought to assess the efficacy of a training intervention to improve prospective memory in those with acquired brain injury. It was hypothesised that those receiving combined GMT and implementation intention training would perform significantly better on the JAAM measures of prospective memory and executive function than those allocated to combined GMT and control imagery intervention. The results of the analysis- as evidenced by the lack of interaction effect- do not support this hypothesis. Although significant differences were observed between the two groups on baseline clinical variables, inclusion of these variables as covariates in the analysis did not influence the observed treatment effect. Furthermore, no significant were differences identified between the two groups on the Removals Task secondary outcome measure. Post-hoc power analysis indicates that the result would not be altered by the recruitment of additional participants.

The apparent failure of the randomisation process is notable, not only because it constitutes a significant aspect of the design, but also because of the implications it may have for an observed effect. The use of blocked- randomisation aimed to reduce the probability of this occurring, and discussion between researchers identified no evidence that concealment was violated. One explanation for the observed inequalities is that the 'block' recruitment from sites contained more severely impaired participants, and this may have exacerbated the influence of any naturally occurring distortions in allocation

process. However, there is no evidence that certain sites contained significantly more impaired participants. Unequal group allocation and disparities in symptom severity do occur in the clinical trials (e.g. Morrison, French, Walford, Lewis, Kilcommons et al., 2004) and while it represents a methodological limitation, is also a foreseeable outcome of any randomisation process.

These issues notwithstanding, some significant differences were observed, with a significant effect of time on the JAAM Total and Prospective Memory scores (specifically event- and time-based prospective memory); however, it is unclear to what extent these improvements in performance represent practice effects or are the result of successful use of the GMT training strategy. Lezak, Howieson & Loring (2004; pp. 116) report that practice effects are more common in tests that have a “large speeded component, require an unfamiliar or practiced mode of response, or have a single solution- particularly if it can be easily conceptualized once it is attained”. The latter two criteria are certainly applicable to the JAAM task, and may increase the likelihood that improved performance is attributable to practice. Alternatively, improvements could have derived from the GMT intervention received by both groups, which is designed to improve planning and problem-solving. Although this is a possibility, it is unclear why there was no improvement to JAAM Planning scores as would have been expected with this training strategy. However, in the absence of a third control group (receiving no intervention at all), firm conclusions on this issue are not possible.

However, this introduces the issue of how the control imagery intervention may have exerted influence in this study. This type of control condition is believed to have a subtly different mode of influence than that of a traditional placebo, which in the context of psychological interventions control for the non-specific factors known to exert a positive influence on treatment effect (e.g. therapeutic relationship). The purpose of the present control intervention was to ensure that participants experienced similar length of intervention and to provide some kind of purposeful cognitive task to engage in. However, it remains unclear whether the use of imagery in the present exercise may have reduced any effect sizes that may have occurred, by potentially exerting an influence through motivational factors.

Certainly, the lack of treatment effect in the present study is contrary to the findings observed in other examinations of Implementation Intentions. Other investigators have found this mnemonic strategy to be effective in improving prospective remembering in a variety of different contexts, including breast self-examination (Prestwich et al. 2005) and blood- glucose monitoring (Liu & Park, 2004). However, in contrast to the participants in the present study, Prestwich et al. (2005) and Liu & Park (2004) looked at the effect of Implementation Intentions in neurotypical adults. More valid comparison may be found with studies exploring the effect of implementation intentions in neurologically-impaired participants.

Kardiasmenos et al. (2008) found that patients with Multiple Sclerosis improved on an ecologically-valid measure of prospective memory task when using an implementation intention-based strategy. Cognitive impairments are associated with MS, although their presence is highly variable, with a significant proportion (34%-46%) exhibiting no observable impairment (Lezak et al., 2004; pp. 250). It is unclear how cognitively impaired Kardiasmenos et al.'s participants actually were, as they did not conduct background clinical assessments. Their sample had a substantially higher estimated premorbid IQ (115) than the present intervention group (93), which is suggestive of their sample being less impaired. In addition, participants received constant feedback on their application of the strategy throughout the task, in contrast to the participants in this study. Alternatively, Lengfelder & Gollwitzer (2001) recruited participants with frontal-lobe brain injury, and found that implementation intentions-based training was effective at improving performance on a dual-tasking paradigm. Their sample possessed significant cognitive impairment, and was thus more similar to the present sample. However, the nature of their task was not only less ecologically valid, but also less challenging than in that used by Kardiasmenos et al. (2008). As such, the effectiveness of Implementation Intentions appears at least partly influenced by the interaction between cognitive impairment and complexity of outcome measure.

This interpretation should be viewed in the context of other remedial interventions for prospective memory deficits. As with those examining Implementation Intentions-based interventions, strategies shown to improve prospective memory have predominantly

occurred in the context of simplified task demands. For example, Levine et al. (2000) found GMT to be effective at improving the quality of participants' performances on a proof-reading task (underlining fruits and vegetables, crossing out liquids and circling numbers), of similar complexity to the dual-tasking paradigm used by Lengfelder & Gollwitzer (2001). Where more ecologically valid (and thus arguably more demanding) tasks have been used (e.g. Sweeney, Morris, Manly & Evans, 2005; Brown & Evans, in preparation) there is little evidence of improvement at a group level. It is possible that the combination of significantly impaired participants and a more challenging task reduces the likelihood of a treatment effect occurring, irrespective of the attributes of the intervention.

Consideration must also be given to how intervention structure may have influenced participants' ability to acquire and apply strategies. The present intervention adopted an errorless learning paradigm to assist with strategy acquisition. Errorless learning is an approach that can assist with learning even in the presence of serious memory deficits (Baddeley & Wilson, 1994). Errorless learning can also be used to aid procedural learning, including dressing oneself and programming an electronic organiser (Evans et al., 2000). Executive deficits are not in themselves barriers to errorless learning; Pitel, Beaunieux, Lebaron, Joyeux, Desgrange et al. (2006) demonstrated that amnesic patients with significant executive dysfunction were able to learn a procedural task using an errorless paradigm. However, while the programming tasks used by Evans et al. (2000) and Pitel et al. (2006) appear quite complex, participants were only required to

make approximately six button presses to be considered 'successful' at learning the sequence. It is unclear whether the effectiveness of errorless learning extends to procedural tasks of the complexity used in the present study, where in contrast to Evans et al. (2000) and Pitel et al. (2006), participants were required to remember eight procedural commands, which were then to be used during unstructured problem-solving.

Another issue is that Pitel et al.'s (2006) participants took 5½ - 7 hours to acquire these sequences, a time far exceeding that available to participants in the present study (45-60 minutes). The influence of intervention duration has been explored by Kennedy, Coelho, Turkstra, Ylvisaker, Sohlberg et al. (2008), who carried out a systematic review of interventions for executive function after traumatic brain injury. They noted that the average amount of time spent in treatment was 12 hours spread over several weekly sessions (Kennedy et al., 2008), and that there were substantial differences in treatment duration, lasting from 30 minutes (e.g. Manly et al., 2001) to 48 hours (e.g. Rath, Simon, Langenbahn, Sherr & Diller, 2003; Kennedy et al., 2008). Successful brief interventions (e.g. Manly et al., 2001; Fish et al., 2007) typically required participants to respond to a discrete stimulus (e.g. text messages saying 'STOP') with a restricted range of responses. There is no necessary relationship between treatment duration and *effectiveness* (Kennedy et al., 2008), although one appears to exist between the length of treatment and the complexity of the behaviour to be performed. The relatively short training time available for subjects in this study may have contributed to the lack of observed effect.

However, in contrast to the factors influencing training acquisition, it was observed that participants had difficulty *applying* strategies, something that may be more closely related to the nature of their deficits. Shallice & Burgess' (1996) model of executive function proposes that development and implementation of a temporary behavioural schema during problem-solving has several components: (1) Problem- orientation; (2) Goal setting; (3) Progressive deepening; (4) Solution checking; (5) Special purpose working memory; and (6) Monitoring of the schema. Episodic memory is also implicated in this process, allowing for comparison with similar problems in the past, while contention-scheduling influences the extent to which a schema is used in future. Assuming that a participant has encoded the training strategies, schema use may break down at one of several points: inadequate analysis of the problem; selection of inappropriate schema as a solution; impaired use of autobiographical memory to guide schema selection; or dysfunctional contention-scheduling.

Successful strategy application may in many ways reflect the demands a strategy places on higher-order functions, and how well training scaffolds these cognitive demands. As was noted earlier, while Implementation Intentions are in their basic form conceptually quite simple ("when I see x, I will do y"), they may difficult for those with cognitive impairment to apply. Thus, for Implementation Intentions to be effective during unstructured problem solving, participants may require a significantly longer and more supported training which addresses a broader range of problems. Indirect support for

this is provided by Kardiasmenos et al. (2008) whose participants were provided with regular prompts to use the strategy over several 'rounds' of the task. Noticeable improvement (according to visual analysis of performance) was only achieved towards the final rounds of the task, potentially reflecting the cumulative effect of training.

A final issue relates to the study design used to assess the effectiveness of this remedial strategy. Randomised controlled trials (RCT) are considered to be the 'gold standard' for assessing the effectiveness of clinical interventions (Altman, Schulz, Moher, Egger, Davidoff et al., 2001). Among the important assumptions that allow them to make causal inferences about a treatment are those of *homogeneity of pathology* and *equivalence of effect*. Homogeneity means that the same pathological process is believed to underlie the disease in all cases (regardless of how patients differ in terms of other demographic or medical factors); equivalence means that disease change is inferred to be a product (directly or indirectly) of changes made to that pathological process. Both of these factors are a necessary to ensure that one is seeing the 'true effect' of an intervention. For example, (assuming certain methodological conditions are met) an RCT looking at the effect of cefotaxine on meningococcal meningitis assesses the 'true' effect of this intervention. This is because meningococcal meningitis is understood to *always* be caused by the same bacterial infection of the meninges (*homogeneity*). Antibiotics (cefotaxine) kill these bacteria and should (directly or indirectly) reduce the severity of disease (*equivalence*). However, any study looking at the effect of cefotaxine on 'meningitis' would be unlikely to assess the true effect of the

treatment because this violates homogeneity and equivalence (meningitis can be caused by bacteria, viral, fungal or parasitic infections), and treatment only acts on one of several possible pathological processes.

The assumptions of homogeneity and equivalence are problematic in the context of neuropsychological impairments because similar behavioural pathology (e.g. deficits in prospective memory), may result from different aetiological pathways (Cubelli & Della Sala, 2011). As such, any response to treatment (or lack thereof) cannot logically be assumed to result from the amelioration (or failure thereof) of the targeted modality. Thus while prospective memory is traditionally conceived as an attentional process (e.g. Burgess et al., 2007), deficits in it cannot be *assumed* to result from damage to attentional systems. For example, patients with dense, anterograde amnesia may experience deficits in prospective memory because they are unable to encode intentions, while they may be unable to use rehabilitation strategies for similar reasons. In this situation, treatment effect could be reduced or absent, independent of any specific qualities of the intervention. These issues are tacitly acknowledged in most RCT trial methodologies; exclusion criteria frequently include those factors known to exert a significant indirect negative influence on treatment effects (e.g. old age, drug abuse; serious psychiatric illness). However, attempts to apply similar standards with respect to influential cognitive moderators in brain injured samples would likely prove problematic. Any such exclusion criteria would be highly restrictive, producing

unfeasibly small samples, limiting the generalizability of results, and providing little information about the reasons for treatment failure.

It is argued that a more practical and ecologically-valid methodology involves the use of neuropsychological and formulation-driven assessment to “account for the observed patterns of spared and impaired abilities in terms of damage to one or more components of a theory or model of normal cognition” (pp.36; Cubelli & Della Sala, 2011; cf. Ellis & Young, 1995). Subsequent allocation of ‘ideal’ and contraindicated cases (according to formulation) to blinded treatment could allow for comparison of treatment effect. As such, clinical case series designs (e.g. O’Neill, Moran & Gillespie, 2010) may more faithful to the principles of clinical neuropsychology, and more appropriate when exploring the impact of neuropsychological interventions.

Limitations

This study contained a number of limitations. The choice of a single-blinded methodology was a practical consideration, but it nonetheless represents a potential source of bias in psychological therapy outcome studies (Wilkes et al., 2007). A related issue is that the scoring of the JAAM outcome measure involves a degree of personal judgement from the assessor, and despite attempts to standardise marking, this could further increase bias within the study. However, one issue for this study relates to the estimate of the sample size required for adequate power. To carry out this calculation, the effect size of the interaction term from the ANOVA in Kardiasmenos et al. (2008)

was drawn upon to estimate the effect size in the present study (albeit the anticipated effect size was conservative compared to the Kardiasmenos et al. result). An alternative approach to analysis may have been to focus on between group differences in mean change scores. If the analysis was a simple between group difference test then a sample size estimate would have indicated a considerably larger sample size would have been required.

Although there is no specific reason to consider that the participants recruited were not representative of the wider population (i.e. no reason to suspect that the effect size would have been any larger with a larger group) it remains possible that the relatively small sample size meant that the participants were not in fact representative of the wider population and a larger sample would have resulted in a larger group x time interaction (or larger between group difference in mean change score). Furthermore, with a larger sample the randomisation procedure may have been more effective in producing groups which were equal in terms of impairment which may have impacted on likely benefit from the intervention in relation to the primary outcome measure (the JAAM task). Finally, there is the potential for sampling bias, in that clinical staff recruited those patients they felt would like to be involved in the study. As such, this may have biased sampling towards more motivated individuals or those with less antisocial behaviour.

Generalizability

Despite these limitations, the present study has a number of strengths in terms of generalizability. It sampled a broad clinical population (ABI), while the demographic composition of the sample in terms of gender and socio-economic status is broadly similar to that seen in clinical practice. However, the small sample size limits the application of these results to the wider population of brain-injured patients.

Conclusions

In conclusion, Implementation Intentions combined with GMT did not significantly improve performance on measures of executive functioning and prospective memory over that of a control intervention. Possible influences on this include the severity and nature of participants' impairments, the structure, duration and intensity of training, and the methodology adopted to investigate this topic.

Clinical and empirical implications

The small observed effect sizes suggest that recruitment of a larger sample alone would be unlikely to alter the present findings. The influence of other variables (e.g. nature and severity of deficits, complexity of desired strategy) means that any future intervention should be more intensive and supportive than in the present study, as well as containing a wider range of behavioural exemplars to aid generalisation. This may in part be accomplished with the adoption of shorter testing sessions, something linked with more

selective use of background measures to characterise the sample. The use of a clinical case series design would allow both for assessment of intervention effectiveness under 'ideal' circumstances, but also for exploration the relative influence of the relevant neuropsychological mechanisms in determining intervention outcome.

While there is currently insufficient evidence to consider Implementation Intentions to be an evidence-based intervention in this clinical population, the relative balance of risks and benefits suggests that this should not necessarily preclude its usage. A key issue relates to those described earlier regarding whether the intervention is sufficiently intensive or provides adequate support to aid strategy acquisition. The issue then arises as to whether- in the absence of compelling evidence- this represents an effective use of resources.

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Chapter 3: Advanced Clinical Practice I- Reflective Critical Account

How to be 'Ethical': coping with uncertainty in everyday Clinical Psychology practice

Andrew Wood*

Academic Unit of Mental Health & Wellbeing

*** Correspondence to:**

Andrew Wood
Academic Unit for Mental Health & Wellbeing
Academic Centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Abstract

This reflective account primarily considers my considerations of ethical issues over the course of their training as well as the role of ethical conduct itself. It includes my recognition that even ethical issues that appear embedded within a specific clinical scenario or incident are themselves a consequence of a wide-ranging number of issues, not immediately associated with that event. These include issues such as the paradigms used to devise both 'pure' and treatment evidence within the research literature, and how these relate to the skills and values held by our profession as Clinical Psychologists. Furthermore, I consider the way in which less specific skills developed throughout training can assist in my resolution of personal concerns, despite the difficulties inherent in challenging one's own beliefs.

Full chapter bound separately in Volume 2

Chapter 4: Advanced Clinical Practice II- Reflective Critical Account

Engaging in and using research as a Clinical Psychologist: Reflections on Socio-political influences.

Andrew Wood*

Academic Unit of Mental Health & Wellbeing

*** Correspondence to:**

Andrew Wood
Academic Unit for Mental Health & Wellbeing
Academic Centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Abstract

This account charts the development of my thoughts in relation to carrying out research as a clinical psychologist. Through this process I have explored my own emotional reactions, moving on to consider the change from the role of a trainee to that of a qualified clinician, including the shifting balance of idealism to pragmatism. Through this reflection I have been encouraged to explore different methods of utilising the research skills that I have developed through my clinical training. Importantly, I have reflected on the influence of socio-political factors regarding how research is used in clinical practice, both in terms of execution and consumption of empirical study.

Full chapter bound separately in Volume 2

Appendix 1- Systematic Review

1.1 Guidelines for submission to “Neuropsychological Rehabilitation”

Submission of manuscripts:

Typescripts. The style and format of the typescripts should conform to the specifications given in the *Publication Manual of the American Psychological Association* (6th ed.). Typescripts should be **double spaced** with adequate margins, and numbered throughout. The title page of an article should contain only:

- (1) the title of the paper, the name(s) and address(es) of the author(s);
- (2) a short title not exceeding 40 letters and spaces, which will be used for page headlines;
- (3) name and address of the author to whom correspondence and proofs should be sent;
- (4) your telephone, fax and e-mail numbers, as this helps speed of processing considerably.
- (5) 3-5 keywords

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

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 page at the beginning of the text.

Permission to quote. Any direct quotation, regardless of length, must be accompanied by a reference citation that includes a page number. Any quote over six manuscript lines should have formal written permission to quote from the copyright owner. It is the author's responsibility to determine whether permission is required from the copyright owner and, if so, to obtain it. (See "[Seeking permission to use other sources](#)" for a template letter to use when seeking copyright permission.)

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

References:

Reference citations within the text. Use authors' last names, with the year of publication, e.g., “(Brown, 1982; Jones & Smith, 1987; White, Johnson, & Thomas, 1990)”. On first citation of references with **three to five** authors, give all names in full, thereafter use [first author] “et al.”.

In the references, the first **six** authors should be listed in full.

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. If a paper is in preparation, submitted, or under review, the reference should include the authors, the title, and the year of the draft (the paper should also be cited throughout the paper using the year of the draft). Manuscripts that are “in press” should also include the publisher or journal, and should substitute “in press” for the date.

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 page, typed double spaced. Titles of journals and books should be given in full, e.g.:

Books:

Rayner, E., Joyce, A., Rose, J., Twyman, M., & Clulow, C. (2008). *Human development: An introduction to the psychodynamics of growth, maturity and ageing* (4th ed.). Hove, UK: Routledge.

Chapter in edited book:

Craik, F. I. M., Naveh-Benjamin, M., & Anderson, N. D. (1998). Encoding processes: Similarities and differences. In M. A. Conway, S. E. Gathercole, & C. Cornoldi (Eds.), *Theories of memory* (Vol. 2, pp. 61–86). Hove, UK: Psychology Press.

Journal article:

Adlington, R. L., Laws, K. R., & Gale, T. M. (2009). The Hatfield Image Test (HIT): A new picture test and norms for experimental and clinical use. *Journal of Clinical and Experimental Neuropsychology*, 31, 731-753. doi:10.1080/13803390802488103

Tables. These should be kept to the minimum. Each table should be typed double spaced on a separate page, 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 and 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. Each figure should be on a separate page, not integrated with the text. 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)".

For more detailed guidelines see [Preparation of Figure Artwork](#).

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, $F(10, 105) = 1.34$, $MSE = 17.70$."

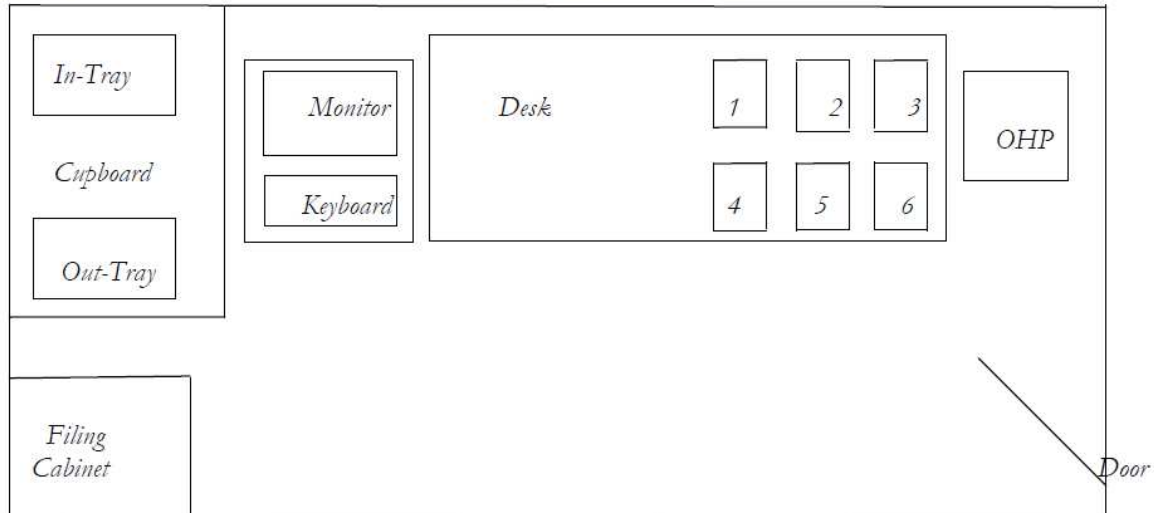
Other tests should be reported in a similar manner to the above example of an F -ratio. For a fuller explanation of statistical presentation, see the *APA Publication Manual* (6th ed.).

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.

Appendix 2- Major Research Project

2.1 JAAM: Instructions for Test Administration

Figure 1: Bird's-eye view of Virtual Reality Office Environment



Key

- 1. Post To Be Sent*
- 2. Agenda Topics*
- 3. Manager's Tasks for Completion*
- 4. Post Diary*
- 5. My Notes for Manager*
- 6. Plan of Action*

The testing area should be set up as shown in Figure 1. Before commencing the formal assessment programme, ensure that the participant is comfortable in navigating around a VR environment by loading the training VR programme at the outset. Ensure that the computer sound volume is audible since part of the task requires the participant to be able to hear certain alarms. Allow as much time as required for the participant to move within the environment; encourage the use of the mouse when navigating around in VR, as this will free up the keyboard for the person running the assessment to press specified keys when the formal assessment begins. This training programme has been specially designed so that there are a number of 'hazards' that have to be overcome. These are generally 'health and safety' issues such as a box having been left in the middle of a corridor, dangerous cables lying around, etc. The programme produces a sound every time one of these is encountered. Ensure that the participant knows how to click on these hazards, as this will allow them to develop the required skill for working with the formal VR assessment, e.g. to focus on selecting specific items on the screen to pick up, put down where they want it, etc.

When the participant has familiarised themselves with navigating around the training VR environment, move to the JAAM VR programme. Follow the script as given, answering any questions as required. It is important for the participant at this stage to become familiar with selecting items by clicking on them, and then clicking on the horizontal surface upon which they wish to place the item. The Office that contains most of the participant's paperwork is the first door on the right along the corridor and the switch for turning on the lights is to the right once the room has been entered. The Meeting Room where the participant will set up the meeting is at the end of the main corridor. It is very important so allow time for the participant to practice this, as otherwise items within the VR environment may 'disappear' or 'distort' thus adding to any initial anxiety regarding the use of the computer. Due to the nature of the programme, objects can sometimes become "lost" when the participant moves them, so that they are no longer visible. As the programme is not designed to test the participant's ability to use it this will not affect the scoring or the participant's performance. Apologise to the participant and explain that this will not affect their scoring. Ask them where they were planning to place that item of furniture and then continue with the programme.

Welcome the participant to the assessment and read from the Script and Scenario, following the instructions in *[italics]*. Ensure that the participant is well-versed in the information given in the script and the scenario sheet – in particular the rules - before proceeding to start the tasks. All questions relating to the running of the assessment should be encouraged before the start of the assessment.

Only questions relating to technical aspects of operating the VR programme, for example, a reminder for how to pick items up, should be answered. If questions arise in relation to how to go about completing the tasks either before or during the assessment, the assessor should refrain from directing the actions of the participant, and refer them to the Scenario Sheet or other relevant instructions available to them. If it becomes apparent that the participant cannot proceed past a particular stage, help should be provided by the assessor to enable the participant to carry on to the next stage of the task, and a note made on the scoring criteria that such a prompt had to be given.

The first task after the Script and Scenario have been read and the participant has understood the 'Manager's Tasks for Completion is for them to write their 'Plan of Action'. After they have completed this first task, put the 'Manager's Tasks For Completion' back in its original place on their desk so that it is not in their way, i.e. they will work from their 'Plan of Action' but they still have access to the 'Manager's Tasks for Completion' if it is needed. Leaving it in accessible like this avoids an additional memory load if they do not write down all the tasks on their 'Plan of Action' since writing the 'Plan of Action' tests planning and is not a memory task. However the participant is informed in the script that they will have to work from their Plan of Action and therefore should write down all the tasks on this. Once the participant has finished writing the Plan of Action, ask if they have any questions and then press "S" to start the timings.

To reduce reliance on having to read documents that arrive in the virtual office from the screen, hard copies are available. These are indicated in red writing in the virtual environment with the physical copies being placed next to the computer during the assessment within easy reach of the participant at the appropriate time. However, there are some documents, four separate memos (please see below for a list of their contents) that will be provided to the participant during the course of the assessment, some of which the participant will know about in advance while others will not be expected. When each memo arrives, a sound occurs on the computer stating “There is a new memo in your in-tray” and the memo will automatically appear in the in-tray in the small office. To read the memo the participant has to click on it in the in-tray and the memo will appear at the bottom right-hand corner of the computer screen. When the memos arrive, allow the participant time to read them and then pass them the paper version. If they do not realise that a memo has arrived, maybe because they are too engrossed in doing something else, please indicate this to the participant and then write this as a qualitative observation on the Scoring Sheet. If they have difficulty opening the memos on the virtual reality environment just use the paper copies.

In situations where a particular participant feels that they have completed all tasks even though this is evidently not the case, prompts should be given to encourage them to undertake remaining tasks in order that appropriate scores can be obtained for the constructs that would otherwise be missed out; again, a note should be made on the scoring criteria that prompts had to be given.

Timings of programme:

These events all occur automatically once the start of the programme has been triggered by the pressing of the ‘S’ key:

- **5 minutes** – Fire Alarm (relates to TBPM)
- **10 minutes** – 1st memo (relates to Adaptive Thinking)
- **18 minutes** – 2nd memo (relates to Prioritisation)
- **20 minutes** – company postman should arrive (relates to TBPM)
- **25 minutes** – 3rd memo (relates to Selection)
- **30 minutes** – Fire Alarm (relates to TBPM)
- **32 minutes** – 4th memo (relates to EBPM)

Memos which arrive in In-Tray

1. From maintenance regarding leak in roof above coffee machine
2. Jobs for cleaner to do after meeting has finished
3. New package from Finance Department
4. First person attending meeting has arrived

2.2 Examiner script for JAAM task

Hello..... I am going to read to you from a script for purposes of continuity. I am going to explain all aspects of the task to you, however if you have any additional questions please ask them at any point.

Thank you for agreeing to take place in this study, which is investigating how well different people work in an office environment. The study takes place in a virtual reality environment on the computer. Do not worry if you haven't used a computer before, clear instructions about how to use the virtual reality programme will be given to you. Would you like to practice using this type of environment before we proceed any further? *[The participant is given the choice of using the training programme]*

I will now let you read, in your own time, the office-scenario in which the assessment will take place. You shall be referred to as the participant and I shall be referred to as the assessor throughout. *[Assessor allows the participant to read the scenario in their own time.]*

Right, now I shall summarise this scenario for you to help you become more familiar with it. This will include only information that you have just read, I will not be telling you anything new.

This study is set in an office, where you will be working as an assistant within the administration department of a large company. Today is your first day on the job, but unfortunately your manager is away so cannot oversee your work. However, they have left you a list of jobs they would like you to complete which will be shown to you shortly. There is a meeting being held today and it is your main priority to ensure that the room for this is set up in time, which will be 40 minutes after you start the study. I will inform you what the exact time will be later. The meeting is for 3 people from your branch of the company, and for 10 external members of the company from other branches. Your other main job involves making sure the post for the rest of the branch is sent, details about this will be provided shortly. There will also be some other time-based tasks which you will need to complete, details will either have been provided for you by your manager or other departments may send you details regarding these. Therefore there are three main categories of tasks for you to do; those to do with the meeting, those to do with the post, and extra time-based tasks. It may be useful for you to perform your tasks around these three categories as much as you can.

Now I will show you around your office. To move around the environment click on these arrows at the top in the direction that you wish to move *[enter the office]*. On your desk you have six sheets of paper, which you also have here in hard copies *[point to real-life copies on their desk]*. These are the Manager's Tasks For Completion, Plan of Action, My Notes For manager, Post Diary and Post To Be Sent, and a list of Agenda Topics *[demonstrate how to pick them up and put them down]*. The purpose of these

sheets of paper will become apparent soon. Please note that you are not required to type anything, everything that needs to be written should be done so by hand on these paper copies just to make things easier for you.

Now can you please identify what other objects you have in your office **[make sure they see the in-tray, completed tray, desk, computer, overhead projector, filing cabinets, sellotape, pens]**. So as you can see you have many resources, but please note that you do not have to use them all if you do not think it is necessary. Also you can only use the resources that you can see in the office.

Now I will show you the room where the meeting is going to take place. The room has already been booked so you do not need to do this **[take them into the meeting room]**. Please can you identify all the objects in here, feel free to move around the room using the arrows if you wish. **[Make sure they identify the coffee machine, the bin, the overhead projector, the 10 tables and stools, the blackboard, the fixed whiteboard and graffiti, the portable whiteboard and the 3 table and chairs at the front of the room]**. Please note that these 3 tables and chairs which are for the internal members of staff to use **[point to tables and chairs at the front of the room]** and this table which the coffee machine is on **[point to table]** are fixed and therefore cannot be moved. The tables and stools at the back of the room, however, can be moved. What you need to do in the meeting room will become apparent once you have read the Manager's Tasks For Completion.

Let's go back into your office and then we can see what tasks your manager has left for you to do **[Go back into their office and hand them the Manager's Tasks for Completion sheet]**. These are your tasks, which your manager has written in a **random** order. Please can you read this list out loud, I will fill in all the blank times just before the study starts **[Participant reads them out loud; give any help or further explanations if needed]**. OK now in your own time please group these tasks on the action plan in the order that you will do them; this should be in the most logical order possible. This list will be taken away from you later so please write as much information as you think you will need to do the tasks on the Plan of Action.

Do you have any questions? This time shown on the clock is 11:00am **[indicate to the clock on the desk]**, which means that the company postman should arrive at 11:20am and the meeting should start in 40 minutes at 11:40am. You may begin your tasks **[press "S" to start the programme at same time as starting the clock]**.

2.3 JAAM Scoring Criteria for Planning and Prospective Memory Tasks*

START TIME:

REQUIRED END TIME:

ACTUAL END TIME:

Construct	Task	Requirements	Points	Qualitative Observations
Planning	Write plan of action (6)	Plan of action is written out taking into account all tasks	2	<u>TIME SPENT ACTION PLANNING</u>
		Plan of action is written out, omitting up to 25% of tasks	1	
		Plan of action written briefly, omitting more than 25% of tasks	0	
		All events regarding meeting placed together, post tasks placed together, and time-based tasks placed together – 10% leeway	2	
		Only events regarding meeting placed together, other haphazard OR more than 10% leeway	1	
		No change/very little change from order on manager's tasks	0	
		Task completed in acceptable completion time	2	
		Task completed in an unsatisfactorily long time	1	
		Failure to complete task	0	
	Arrange furniture for meeting (4)	All external members of the meeting can see the whiteboard	2	<u>PLAN OF FURNITURE</u> <u>TIME SPENT ACTION PLANNING</u>
		25% of the external members cannot see the whiteboard or 25% have their backs to the internal members of the meeting	1	
		The chairs and stools are in a totally random arrangement	0	
		Task completed in acceptable completion time	2	
		Task completed in an unsatisfactorily long time	1	
		Failure to complete task	0	
Action-based Prospective Memory	Update the post diary when new package needs to be send (2)	The new parcel is added to the post diary immediately	2	
		The new parcel is added to the post list but at a later date, i.e. after checking the action plan at the end of the task, OR written on "Notes for Manager"	1	
		The post diary is not updated	0	
	Record if any of the equipment breaks (2)	It is recorded on the "Notes for Manager" when the OHP breaks	2	
		It is recorded on the "Action Plan" when the OHP breaks, or only after referring to the "Action Plan"	1	
		Nothing is written down	0	
Event-based Prospective Memory	Note the times of the fire alarms (2)	Both alarms are recorded on the "Notes for Manager"	2	<u>TIMES OF FIRE ALARM</u>
		Only 1 alarm is recorded, they are written on the "Action Plan" or are written only after referring to the "Action Plan"	1	
		None of the times are recorded	0	
	Turn on coffee machine when	Turn on the coffee machine after the memo arrives without referring to the "Action Plan"	2	

	the first person arrives (2)	Turn on the coffee machine after referring to the “Action Plan”	1	
		The coffee machine is not turned on, or it is turned on before the memo from reception arrives	0	
Time-based Prospective Memory	Turn on projector 10 minutes before the meeting starts (2)	Turn on projector at exact time	2	
		Turn on projector but not at designated time	1	
		Never turn on the projector	0	
	Indicate whether the company postman has arrived (2)	Write down that the company postman has not arrived and be aware that the post must be sent another way	2	
		It is not recorded that the company postman has not arrived but the post is sent another way	1	
		Do not notice that the company postman has not arrived to take the post	0	

* Adapted from JAAM Manual (Jansari, 2009)

2.4 Participant Information Sheet



University
of Glasgow



Participant information sheet **Rehabilitation of Prospective Memory [B]**

Purpose of this study

This study aims to test whether a treatment for memory problems following brain injury is effective. It looks at a particular kind of memory called 'prospective memory'; this is the memory for things you need to do in the future. For example, if you need to remember to take medication at a certain time or phone a friend. Many people have problems with these kinds of tasks after they have experienced a brain injury.

If I decide to take part, what will happen?

You will already have completed two assessment sessions in an earlier study. You will be asked to attend one session at the same location where this testing is carried out. Where possible this will be at the NHS or voluntary organisation where you were recruited from. It is not possible to only participate in the treatment session.

This session will last a maximum of 2 ½ hours. First, you will be randomly placed into an intervention group. This intervention will last about 1 hour and will get you practicing skills and techniques to help you with your memory, using things like imagery and other strategies known to help people with brain injury. After that you will get a short break. Finally you will complete two computer tests similar to ones you did before, where you can practice these skills.

Research methods

This is an intervention study, which means it looks at whether a treatment works or not. It compares two groups; one group who receive the full treatment, another group that receives a treatment that isn't expected to work (a 'placebo' treatment). People are randomly placed in one of these groups. This study is also 'blinded', which means that you would not know whether you are receiving the full or placebo treatment. This kind of study means that you are not able to pick which group you will be in, and the experimenter will not be able to tell you. Therefore, it is possible that you will not be in the 'full treatment' group, but believe that you are. However, even if you do not receive the full treatment at this stage, you will still have the chance later on, if the study shows it to be effective.

Why have I been chosen?

This study looks at people who have problems with prospective memory following a brain injury. You, someone you know or earlier assessment has suggested that you may experience difficulties with this.

Do I have to take part?

No. It is entirely optional whether or not you take part. If you decide not to take part, this will have no impact on the care or treatment you receive in the NHS.

Are there any disadvantages to taking part in this study?

The tests we will use are meant to be challenging. This means that people can find them quite tiring to complete.

As was mentioned earlier, you may be given the ineffective 'placebo' treatment, but not know it until after the study. This can cause some people to feel that they have been misled. This is a possibility, but it is not our intention to cause distress. The decision to 'blind' a study is an important part of making this research useful. You can discuss your feelings with any of the people detailed at the end of this information sheet.

What are the possible benefits to taking part in this study?

It is hoped that if you continue to use the skills learned during the intervention, this will help improve your prospective memory (e.g. remembering to pass a message onto a friend when you see them). Both the full treatment and placebo groups will receive treatment if this is found to be effective. In this way, you will receive the best treatment available regardless of which group you are in. Even if this is not the case, this study will still lead to new knowledge to help others with brain injury and these types of memory problems.

What alternative treatments could I get?

There are a limited number of treatments available for this type of memory problem. This study combines the only other effective training treatment with a newer approach using imagery.

Will you contact my GP?

With your permission, we will send your GP a short letter to let them know that you are taking part in the study. If you would like to see an example of the standard letter that we would be sending, please just ask a member of the study team.

What kinds of expenses or costs can I claim?

You will not be paid to take part in this study.

Who has reviewed this study?

This study has been reviewed by the Department of Psychological Medicine at the University of Glasgow; NHS Greater Glasgow & Clyde Research and Development Department; and the NHS Greater Glasgow & Clyde Ethics Committee. They have approved it to begin recruiting participants.

Who is organising and funding this research?

This study is being conducted to fulfill the requirements for the Doctorate in Clinical Psychology and the Doctorate of Philosophy (PhD) in Psychological Medicine at the University of Glasgow. It is being conducted by Trainee Clinical Psychologists Andrew Wood and Fiona Scott, and PhD student Satu Baylan. It is being supervised by Professor Jon Evans at the Department of Psychological Medicine (University of Glasgow). Financial support is being provided by the University of Glasgow, NHS Greater Glasgow & Clyde and the Sackler Institute of Psychobiological Research.

What if I decide I want to drop out?

You can decide to withdraw from the study at any point. You do not have to give a reason. It will have no impact on the quality of the care you receive.

If I have any further questions?

If you would like more information or would like to receive a summary of the main findings once the study has completed, please contact:

Andrew Wood or Fiona Scott

(Trainee Clinical Psychologists)
Section of Psychological Medicine,
Gartnavel Royal Hospital, 1055 Great
Western Road, Glasgow, G21 OXH.
Tel. 075 3646 6149
E-mail: f.scott.1@research.gla.ac.uk or
a.wood.1@research.gla.ac.uk

Satu Baylan

(PhD Student)
Sackler Institute of Psychobiological
Research, Southern General Hospital,
Glasgow, G51 4TF.
Tel. 0141 232 7566
E-mail: s.baylan@clinmed.gla.ac.uk

If you would like to contact someone, who is not directly involved in the study, for general advice about taking part in research, please contact Dr Denyse Kersel, Clinical Director, Community Treatment Centre for brain Injury, on 0141 300 6313 or via email:
denyse.kersel@ggc.scot.nhs.uk.

Thank you for taking the time to read this information.

2.5 Participant Consent Form



University
of Glasgow



CONSENT FORM

Rehabilitation of Prospective Memory

Names of Researchers: Andrew Wood, Fiona Scott and Satu Baylan

Please initial box

1. I confirm that I have read and understand the information sheet dated 25 August 2010 (version 2.1) for the above study. ☐
2. I have had the opportunity to consider the information provided, ask questions, and had these answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected. ☐
4. One of the tests require your responses to be recorded using an audio recorder (1-2 minutes) for scoring purposes. This will be stored anonymously and will not be used for any other purpose. I give permission to record my answers. ☐
5. I agree to make information collected during this study available to related research projects at the Section of Psychological Medicine, University of Glasgow. ☐
6. I give permission for my test scores to be given to my clinical team to help them in planning my treatment. ☐
7. I give permission for my GP to be informed that I am taking part in the current study. ☐
8. I agree to take part in the above study. ☐

Name of subject

Date

Signature

Name of Person taking consent

Date

Signature

2.6 Protocol for Goal Management Training and Implementation Intention Intervention. (GMT protocol adapted from Levine et al. (2000)).

Before the participant is in the room:

- Have laptop switched on, with 'Beep/ buzzer' mp3 file accessible.
- Place a mug behind the participant's chair
- Place participant instructions in front of the seat
- Invite participant into the testing room.

Begin treatment protocol.

Regardless of the participant's grasp of the techniques or performance, encouragement should be given following all attempts. Checks should be made to ensure that they understand the tasks or instructions. The treatment script will include the steps outlined below. At each point turn over the appropriate page and get the participant to read out the steps.

Stage 1- Goal Management Training

"Thank you for taking part in this study. As it said in your information sheet, the purpose of this study is to improve your memory. You will practice techniques that will help you remember to do things in the future.

It is often very useful if what we do today relate to your real-life experiences. So when we're doing these things, try to think about how you could use them in everyday life, even if it's just with little things. Some of the things I ask you to do may feel a bit unusual, but they are very helpful. I will also ask you to do these things several times. This is a special technique that will help you to remember things more easily.

In order to remember to do things, first you need to have a good plan for what it is you want to do. People often find planning and solving problems harder after a brain injury. When they see a problem, they often charge at it full speed without thinking about whether their solution will work! It is a bit like a waving a red rag in front of a bull! Can you think of a time you've charged straight in?



They can also find it more difficult coming up with a solution that works. So we'll start by finding ways to come up with good solutions to problems.

When you're faced with a problem the first thing you need to do is "**STOP**". Finding a solution isn't a race. Take your time. Some people might say, "Wait a minute" or "hold on"

to themselves. You can come up with your own if you like. What would you say to bring yourself to a halt?

- STOP!

After you've stopped, you need to decide what it is you'd like to happen. You need to work out your **goal** or **target**.



For example, if someone asked you to 'take the rubbish out', what would this mean. How would you know that you'd successfully 'taken the rubbish out'? What would it look like? Try to picture it in your mind. Think about the way it would look if it were done properly.

Give them time to think. Present the corresponding participant sheet.

- STOP!
- Ask yourself, "What is my goal"?

Next you need to describe in detail what your goal will look like if you achieve it. In my example, it would be that I could imagine a tied up bin bag sitting in the rubbish collection area. Can you think about that?

Give them time to think. Present the corresponding participant sheet.

- STOP!
- Ask yourself, "What is my goal"?
- What will my goal look like if I have achieved it?

However, to achieve a goal we need to **list the steps** we have to take to get there. So to take out the rubbish, I'd first get out new bin liner. Then I'd take out the full bag and tie it. Next I'd put the clean bin liner in the bin. Finally, I'd take the bin bag outside to the collection area.



Everyone's steps will be different, but think about how you'd do it?

Give them time to think. Present the corresponding participant sheet.

- STOP!
- Ask yourself, "What is my goal"?
- What will my goal look like if I have achieved it?
- Break it down into smaller steps

To make sure you remember what it is you're going to do, it helps to **learn the steps**. Try picturing them in your mind. If you can't picture yourself going from start to finish in one steady stream, you may have missed out a step. Go over them several times until you're happy that you can remember them.

- STOP!
- Ask yourself, “What is my goal”?
- What will my goal look like if I have achieved it?
- Break it down into smaller steps
- Learn the steps

Get the participant to repeat the list with it in front of them.

“Now let’s practice this. If somebody said to you **“Can you make me some tea?”** how would you do that using these skills? Talk me through it”. [Scaffold the participant’s attempts, with the minimum amount of assistance possible].

Stage 2- Implementation Intentions

“We’ve now looked at ways of planning more effectively. This is an important part of remembering things. Now, we’re going to look at ways of helping you to remember to do things. Research has shown that it can be very useful to use your imagination when trying to remember things. It has also shown that speaking things out loud can also be very helpful. I am going to ask you to practice some techniques. Some of them can feel a bit unusual, but they’re very useful.

(1)

“First, I’d like you to think of a time when you forgot to do something. Can you tell me your example? [*If the participant can’t think of an example, prompt with ‘forgetting your medication’, ‘forgetting to meet a friend’ or ‘forgetting to post something important’.*”

- Can you tell me what happened in a bit more detail?
- What were you meant to do?
- What happened because you forgot?
- Did forgetting have a good or a bad outcome?
- Would you want that to happen again?

“Often there is a sign, cue or trigger to let you know that you have to do something. Sometimes this sign is a thing, sometime it’s a behaviour or action, other times it’s inside our heads. So, for example, if I said to you “after this session is over, can you put the chairs away”, the cue might be you getting up from your seat, opening the door to leave, or seeing that 1 hour has passed. Its up to you what it is, but it has to happen at the right time for you to complete the task.

“This means that whenever you are trying to remember to do something, you first thing you need to work out the **cue-to-act**. To do this, you must plan what you need to do. You’ve worked on this already. If you have to do something in the future, you need to work if there

is a prompt or cue letting you know when to act. And if there is, what it is. So starting from the beginning, when you realize there there's something you need to do later on:

- STOP!
- Ask yourself, "What is my goal"?
- What will my goal look like if I have achieved it?
- Break it down into smaller steps
- Learn the steps
- What's my cue (It can be a smell, a sound, an event, a specific time or gap)?

"So in your example, what do you think might have been the cue? [*Work through this example with the participant*]

Questions for elaboration: How did you know it was time to take it? What made you think that? What might have happened at the same time?

(2)

"The next thing is to imagine what you'll do when you hear the prompt or cue. Picture the scene in your head. Imagine all the things going on around you. Picture the cue very clearly. Pull in all five of your senses. Imagine the cue happening and you acting straight away. Go from start to finish. Imagine noticing the cue and go all the way through to you completing the task you're meant to do. Do it a couple of times to be sure you've got it. So, for example, if you thought to yourself, "when I get home, I will need to call my friend", you might imagine yourself walking in the door of your home, walking over to the telephone, and calling her straight away.

So starting from the beginning, in your example:

- STOP!
- Ask yourself, "What is my goal?"
- What will my goal look like if I have achieved it?
- Break it down into smaller steps
- Learn the steps
- Work out your cue (It can be a smell, a sound, an event, an action, a specific time)?
- Imagine the cue happening, and you acting straight away. Make it very clear.

(3)

Once you done this, play with the image. Imagine the cue you've picked. Make it bigger and more noticeable. If it's a sound, make it louder. If it's an object, make it bigger. If it's a smell or sensation, make it stronger. If it's an action, make it exaggerated. Make your cue very clear in your mind. Think about the other things that will be going on around you at that.

"If you need to watch out for a special time, imagine hearing anything to do with 'time', clocks or watches and acting straight away. Is there anything that will happen at that special time? Imagine a clock or a watch. What will it look like when it's time to act? What time will it tell? How often will you need to check it? Imagine yourself checking the clock or watch regularly.

So in your example...

So starting from the beginning, in your example:

- STOP!
- Ask yourself, "What is my goal?"
- What will my goal look like if I have achieved it?
- Break it down into smaller steps
- Learn the steps
- Work out your cue (It can be a smell, a sound, an event, a specific time or gap)?
- Imagine the cue happening, and you acting straight away. Make it very clear.
- Play with the cue. Make it more noticeable.

(4)

After that, say what you're going to do out loud. Saying your intention out loud may feel a bit strange. But it means that if you go to the trouble of saying something out loud, it shows that you've really thought about it.



"For example, "when I see/hear/smell/do [whatever]... I will..."

So starting from the beginning, in your example:

- STOP!
- Ask yourself, "What is my goal?"
- What will my goal look like if I have achieved it?
- Break it down into smaller steps
- Learn the steps
- Work out your cue (It can be a smell, a sound, an event, a specific time or gap)?
- Picture the cue happening, and you acting straight away. Make it very clear.
- Play with the cue. Make it more noticeable
- Say out loud, "when I notice the cue, I will do ..."

[This stage again uses errorless learning. Ask the participant to read out the bullet points.]

Stage 3- Practice

[Ask if they have any questions, and correct any misunderstanding about the techniques]

“That might seem like a lot. But, soon you’ll see how naturally and easily it comes. Let’s practice.

The practice examples include a mixture of direct and indirect directions. Use heavy intonation to indicate the relevant requests. Leave longer-than-usual gaps if necessary. If they don’t pick up hints, explicitly describe the tasks.

Direct requests and well-structured problems:

- ***“As you’re looking through these drawings, when you see the card with a cat on it, tell me the colour of its coat”.***

“Tell me how you’d use your skills to remember to do this”.

Support them in this first exercise, but try to provide the minimal amount required for success. Provide significant encouragement regardless of performance.

“Let’s try a new one”

- ***“When you finish here today, if the light in the hallway is off, switch it on.”***

“Tell me how you’d use your skills to remember to do this.”

Indirect requests and ill-structured problems:

“Let’s try a new one”

- ***“The chairs need to be put away once the test is over”.***

“Tell me how you’d use your skills to remember to do this”.

“Let’s try a new one”

- ***“The receptionist wanted the clock back when we finish”.***

“Tell me how you’d use your skills to remember to do this”.

However sometimes you may need to more than one thing at a time. Sometimes you may just need to stop and work out the steps. Other tasks will mean you need to find a cue. Sometimes you might need to do both. It is up to you to work out if there’s a cue that needs to be noticed. If you start by working out the steps, you can then work out whether there you need to find a cue. Do it one step at a time.

So, see if you can work it out in this task:

“I want you to sort these playing cards for me according to colour. But while you’re doing that, when you hear the sound of the buzzer, I want you to tell me the name of an animal”. Play the sound of the bell, and then say, ***“Talk me through the process. Tell me what you’d do, and how you’d do it”.*** Support them in this first exercise, but try to provide the minimal amount required for success. Provide significant encouragement regardless of performance.

Okay, let's practice these skills for real. You're not getting tested on this. It's just a chance to try out what you've learned. You don't need to tell me what you'd do, just use the techniques.

[The task itself will ask participants to circle capital letters and to put a line through names in a large bit of text. These instructions will be left in front of them throughout the test. The task will last between **4-6 minutes**].

I have a couple of things I'd like you to try (place the tasks in front of the participants, but remove after training). On this bit of paper, I'd like you to circle the capital letters and put a line through the names. However, while you're doing this:

- **When you hear the sound of the buzzer (play sound of buzzer), can you stop what you're doing, pick up the mug behind you and give it to me?**
- **Every 2 minutes, can you tell me the name of a different film, TV or radio programme?**

Can you tell me what I've asked you to do?

Tell me when you're ready to start.

Place the clock on the table in front of them. Have the buzzer sound file available.

After the task has finished:

That's great work. Now you've practised these skills, I'd like you to use them in the next assessment measures you do after your break. Think about how you'd use them in the computer task we did earlier.

Give the participant the final sheet to consider over the break.

2.7 Protocol for Placebo Intervention

[Placebo intervention included identical Goal Management Training component and practice session to that of the experimental intervention in Chapter 2.5]

Stage 2- Placebo

We've looked at ways of planning more effectively. Now, we're going to look at ways to help you remember to do things in the future. Research has shown that it can be very useful to use your imagination when trying to remember things. It has also shown that speaking things out loud can also be very helpful. I am going to get you to practice some techniques. As I said earlier, some of them can feel a bit strange, but they're very useful.

There are a few parts to this. We're going to use something called Neural Spreading Activation to use images to improve your memory. This works by creating connections between things that are important in your life, and the things you want to remember to do during the day. This process produces superior learning because it allows you to use several methods of encoding (such as emotional responses and imagery) to assist your memory. First, picture someone you know well and have strong positive feelings towards (select). The better you know the person, the more parts of your life they will connect to. Think about their face in detail. Make their face bigger and bigger; more and more detailed (enlarge). Take the first letter of the cue that you have chosen. Try using some feature or combination of features in the person's face to form the first letter of the cue. For example, if the cue begins with the letter L (for light), then a 'L' might be traced using a line running along the eyebrows, curving around the eyes to the tip of the nose, from there, round the corner of the mouth, and back towards their chin.

[Place the treatment script in front of the participant. If the participant asks 'what is a cue', give a time-based PM example (e.g. going to the doctors at 5 o'clock- "5 would be your cue". Then state that it will become clearer with practice.) Present the picture of the experimenter with an '5' superimposed on it]

So...

- STOP!
- Ask yourself, "What is my goal?"
- Break it down into smaller steps
- Learn the steps
- Work out your cue
- Use your imagination to trace the first letter of the cue on a friend's face

Now you know what you're trying to do, and how you're going to do it. Picture the person's face very clearly. Imagine their face getting bigger and clearer. Take the first letter of the cue. Make it very clear in your mind. Make the letter very distinctive. Use the person's facial features to trace the letter. Use their eyes, eyebrows, mouth, nose, hair. Do it a couple of times to be sure you've got it.

[This stage again uses errorless learning. Ask the participant to write the word down on a small bit of paper as they're read out].

2.8 **Major Research Project- Proposal**

Title: Rehabilitation of Executive function deficits following Acquired Brain Injury: using Goal Management Training and Implementation Intentions to improve Prospective Memory.

Abstract: Background: Deficits in executive function (e.g. planning, problem-solving, prospective memory) following brain injury are associated with significant negative social and occupational outcomes. Prospective memory (PM) is particularly susceptible to the effects of brain injury, as it relies on controlled attentional resources to establish and recall intentions. Implementation intentions (II) have been shown to improve performance on prospective memory tasks across a variety of durations, by circumventing controlled attention and establishing strong cue-action associations using imagery and declarative statements.

Aims: To determine the efficacy of a theory-based training intervention for prospective memory deficits following acquired brain injury.

Methods: A single blind, randomised trial will be used to assess the efficacy of implementation intentions for individuals with acquired brain injury. A within-between mixed design will be used to assess pre/ post intervention changes between two groups receiving either implementation intentions or a placebo interventions. Participants will be assessed using traditional and ecologically valid measures of executive function.

Applications: This study aims to increase the number of evidence-based interventions for deficits in executive function by demonstrating the efficacy of implementation intentions in a brain injury population.

Introduction

Executive function refers to the higher-order processing of internally- and externally-generated stimuli (Burgess et al., 2007), and includes abilities such as planning, concept formation, impulse control, metacognition and self-monitoring. Deficits in executive function have been associated with significant impairment in everyday functioning, leading to poor vocational and social outcomes (Mazauk et al., 1997). Executive deficits have historically been conceptualised as a largely homogenous syndrome, such as ‘frontal lobe syndrome’, and most recently ‘dysexecutive syndrome’ (Burgess et al., 2006). However, recent investigations have questioned the validity of this syndromal perspective (e.g. Stuss & Alexander, 2007), with more comprehensive models acknowledging the separation of function within a broader attentional system.

In their influential model of executive function, Shallice & Burgess (1996) delineate the processes involved in the executive system used for complex everyday tasks. They propose that in response to a given situation, individuals construct temporary new schemas (behavioural templates or protocols used to achieve a goal). This can occur spontaneously, or through a process of problem solving (an iterative cycle involving problem formation, deepening of the solving attempt, and establishment of a ‘success criteria’ against which later solution attempts are compared). Once developed, schema are implemented in accordance with ‘contention scheduling’ (the process of choosing between well-established action sequences and thought processes; Burgess et al., 2007). However, to function efficiently in real-world tasks, two special purpose processes are used: Firstly, to reduce the cognitive load associated with constructing new schema, an episodic/ autobiographical memory system is used to provide similar experiences when confronted with novel situations and problems. Secondly, where schema are not to be implemented immediately, a prospective memory (PM) component assists in creating and realizing the schema later.

This prospective memory component appears to be particularly susceptible to the effects of brain injury, with deficits frequently appearing following injury (e.g. Shum, Valentine & Cutmore, 1999). Failures in prospective memory are both familiar and important, as they

range from the benign but irritating (forgetting to post a letter or meet a friend), to the potentially disastrous (leaving pots burning on the stove). Shallice & Burgess (1991) argue that having identified a 'to-be-remembered' task, a person creates an 'intention marker', a neural trigger represented within a three-dimensional cognitive space. When a person's conscious attention encounters an intention marker, it brings the intention into awareness and inhibits current ongoing activity.

It is argued that failure in prospective memory is frequently a result of 'goal neglect' (Duncan, 1996) or 'strategy application disorder' (Shallice & Burgess, 1991). While these two deficits give rise to subtly differing patterns of behaviour, they both result in the failure to carry out appropriate activities given a relevant intentional cue. Importantly, this is in spite of accurate verbal recall of the intention to be carried out.

There are two forms of prospective memory tasks: time-based (remembering to do something at a particular time e.g. cooking, meeting a friend), and event-based (remembering to do something on the occurrence of a specific prompt). It has been argued that time-based prospective tasks provoke a considerably greater cognitive load than event-based remembering, particularly given the absence of environmental cues to provoke recall (Einstein et al., 2005, Kvavilashvili & Fisher, 2007). Factors that have been shown to influence event-based recall include cue salience, relevance, the propositional structure of intentions and the strength of cue-intention association (e.g. McDaniel & Einstein, 2000; McDaniel et al., 2007).

Explanations for time-based prospective memory have received significantly less attention (Kvalilashvili & Fisher, 2007), with the competing models being the test-wait-test-exit model (TWTE) and random-walk models (Harris & Wilkins, 1982; Wilkins 1979). TWTE argues that successful performance is dependant on monitoring of the time, possibly using an internal clock, accompanied by occasional checks that increase in a J-shaped curve towards the target time. Alternatively, according to the random-walk model of prospective memory, the intention sits within a multidimensional representation of consciousness, triggered only when the person's attention accidentally stumbles upon it or closely related concepts within

the internal or external environment (e.g. events or concepts relating to *time*). As compared to the TWTE model, the random-walk model implies that few- if any- attentional resources are required to trigger a time-based intention.

A number of interventions have attempted to rehabilitate deficits in prospective memory; however, in considering them, an important distinction must be made between rehabilitation approaches aiming to compensate for deficits (by providing neurological and/or environmental support for a deficit), or those that seek to ameliorate deficits through training (Evans, 2006). Manly et al. (2002) and Fish et al. (2007) adopt the former approach, using intermittent prompts to cue prospective memory tasks in patients with traumatic brain injury. They found that even when prompts were semi-random, and were non-contingent with the cue, they nonetheless produced significant improvements in performance compared with controls. Manly et al. (2002) argue that the prompt provides external support for intentional markers that are competing for expression, orienting attention away from the immediate task. This explanation is consistent with Burgess et al. (2007) 'gateway hypothesis' of attentional control, which argues that aspects of Brodmann Area 10 (lateral and medial rostral) are responsible for mediating between stimulus-oriented and stimulus-independent cognition; essentially switching between the outside environment and one's internal goals.

Remedial or skills-based interventions for PM deficits can be divided into those looking at Goal Management Training (Robertson et al., 1996) and Implementation Intentions (Gollwitzer, 1999). Levine et al. (2000) randomised participants with brain injury to either Goal Management Training (GMT) or Motor Skills Training (MST), and assessed their performance on proof reading task (participants were to circle numbers, underline fruits and vegetables, and put an 'X' through liquids). They found that those assigned to GMT were significantly more accurate and slower than the MST group, taken to indicate greater care and attention to the task in hand. However, other studies have provided equivocal support for the use of GMT in prospective memory. Brown & Evans (in preparation) assessed PM performance on a virtual reality task following brief GMT training and auditory alerts, with the treatment group showing improvement on a measure of event-based PM.

There was no overall improvement on other measures of time- and event-based PM (although this may be due to ceiling effects on the task performance).

However, there are important qualitative differences between the tasks used in these studies, and these null findings may reflect incompatibility between GMT and specific PM tasks. For example, the proof-reading task used by Levine et al. (2000) is a highly structured PM task, akin to those used in experimental investigations of PM. It is possible that given a task where an individual is engaged in spotting stimuli (with few- if any- distractions), the intention remains in conscious attention throughout. However, when an intention is to be activated while the individual simultaneously performs other demanding tasks (e.g. Brown & Evans, in preparation), GMT may not in itself provide sufficient assistance, even with auditory alerts to remind them of their training. Nonetheless, GMT is likely to be a critical part in the process, as it supports the development of clear planning.

In contrast, implementation intentions (II) are explicit statements about their intentions when they see a particular cue (e.g. 'when I see X, I will do Y'), and includes the use of imagery to create a rich mental representation of possible stimuli that may occur with the cue. Implementation intentions are believed to work, not only because they establish a strong, cue-response association, but also because they circumvent the need for controlled attention to realize the intention. Importantly, II have been shown to be effective in both event- and time-based PM tasks. For example, Prestwich et al. (2005) used II to promote breast self-examination, and found that a statement of the specific intention and commitment to self-examining in the next month was found to increase both the likelihood and frequency of self-examination at one- and six-month follow-up. Similarly, Liu & Park (2004) looked at the effect of II on accuracy of blood glucose checking in older adults, and found that those using II performed tests nearly 50% more often than controls over a period of three weeks. This study also suggests that II may work even where there are no inherent motivators, as none of the participants had diabetes.

Using a neurologically impaired sample, Kardiasmenos et al. (2008) allocated patients with Multiple Sclerosis to II and control conditions, following which they were then tested on a

board game meant to simulate prospective memory in everyday life. They found a significant difference between the MS intervention and control groups, with the intervention group showing a greater proportion of correct event-based PM responses in the task. Lengfelder & Gollwitzer (2001) found that II had a significant effect in improving dual-tasking performance in those with frontal brain injury. However, the practical implications of this study are unclear, as the authors did not explore the impact of II on functional or ecologically valid measures.

Consequently, there is a need to explore the impact which II have on PM performance in those with brain injury. The present study will explore the impact of implementation intentions in the context of Shallice & Burgess' (1991) model of realisation of intentions: that for intention formation and realization, there must be adequate problem solving. Therefore, all participants will receive GMT; however, only half will receive an implementation intention intervention.

Aims and hypotheses:

This study aims to:

- Determine the efficacy of a theory-based training intervention for prospective memory.
- Establish whether individual profiles of deficits predict the improvement obtained from a particular intervention.
- Explore predicted dissociations in response to the intervention according to the deficits identified by the baseline assessment measures.

Hypotheses

1. Participants receiving combined GMT and implementation intention training will perform significantly better on measures of prospective memory and executive function than those allocated to combined GMT and placebo intervention.

2. Those participants with the greatest deficits in PM at baseline will derive significantly greater benefit from the II intervention than those with better performance at initial testing.

Plan of Investigation

Participants

Twenty-six participants with acquired brain injury (ABI) with reports self- and/or carer reports of executive function deficits will be recruited. Carers will be used to complete proxy measures of questionnaires. Their completed questionnaires will be used to characterise the brain injured sample; they will not be recruited to the study as experimental participants nor are they control subjects. Their consent will be implicit if questionnaires are returned completed.

Inclusion Criteria

Brain-injured participants between the ages of 18 and 65 and reported deficits in executive function from self and/or carers will be included.

Exclusion criteria

Individuals with premorbid learning disability, concurrent severe mental illness, currently abusing drugs or alcohol, or with degenerative neurological disorders will be excluded. Factors such as severe dyslexia and visual impairments, and inability to provide informed consent (e.g. Adults with Incapacity (Scotland) 2000 Act) will also merit exclusion. Those with severe unawareness of deficits will also be excluded.

Recruitment procedures

Participants will be recruited from NHS services, such as Community Treatment Centre; Neuropsychology departments and Stroke services in Glasgow and Ayrshire & Arran. Further recruitment will also occur from organisations such as Headway (Dumbarton and Ayrshire &

Arran), Momentum, and Graham Anderson House, Springburn. Clinical judgement will be used to assess suitability and capacity.

Measures

The following baseline neuropsychological measures will be used to characterise the sample:

- Adapted Dysexecutive Questionnaire [carer version] (DEX; Chaytor et al., 2006) which assesses general dysexecutive symptoms, as well as coping behaviours.
- Prospective and Retrospective Memory Questionnaire [patient and carer versions] (PRMQ; Crawford et al., 2003; 2006).
- Wechsler Test of Adult Reading (WTAR; The Psychological Corporation, 2001) as a measure of premorbid intellectual functioning.
- Rey Complex Figure Test (Immediate and Delayed) (Meyers & Meyers, 1985) as a measure of visual memory.
- Logical memory (Immediate and Delayed) subtests of Wechsler Memory Scale (WMS-III) as a measure of verbal memory.
- Symbol-digit Modalities Test (Smith, 1968) as a measure of processing speed.
- Matrix Reasoning subtest from Wechsler Adult Intelligence Scale (WAIS-III; Wechsler, 1997) as a measure of non-verbal or fluid intelligence.
- Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1989).
- Tower Test (D-KEFS, Delis-Kaplan Executive Function System; Delis, Kaplan & Kramer, 2001), as a 'traditional' measure of executive function.
- Trail Making Test (Reitan 1958) as a measure of set shifting.
- Cambridge Prospective Memory Test (CAMPROMPT; Wilson et al., 2005).
- Modified Hotel Test as an ecologically valid measure of executive function.
- Computerized tasks with and without prospective remembering demand.

A measure of Socio-economic status will be determined using the Scottish Index of Multiple Deprivation (SIMD) system based on the participants' postcode.

Primary outcome measures

- JAAM Virtual Reality test (Jansari, Agnew, Akesson & Murphy, 2004) will be used pre- and post- intervention. The JAAM is a computer-based task which requires participants to complete PM tasks, such as responding to memos, within a virtual office environment. Participants receive separate scores for planning and PM components, which contribute to a total measure of executive function.
- Removals Task (Third Dimension, 2005) will be used post-intervention to assess for generalisation of strategies. This is a computer-based task which requires participants to remove items of furniture from a house, while completing certain PM tasks (e.g. remembering to close doors, checking the front door after a set period). Due to ceiling effects observed in Brown & Evans (submitted) a modified version with an auditory monitoring task will be used.

Design

A 2x2 mixed prospective design will be used. The between-subjects variable will be *intervention* (GMT+ Implementation Intentions vs. GMT+ Placebo imagery intervention), and the within-subjects variable *time* (baseline and post-treatment). Participants will be randomised to one of two groups using a true random number generator (e.g. random.org; Haahr, 2010) immediately before the second testing session. This is a single-blind randomised trial; participants will be blind to treatment allocation, however experimenters will not be blind to treatment or assessment allocation.

Research Procedures

Participants will undergo the all of the above assessment measures (except the Removals Task) over two testing sessions. Assessment may be undertaken either as part of involvement in a linked study (“Assessment of Everyday Executive Functioning in Individuals with Acquired Brain Injury”) or as part of the present study. Each session will last a maximum of 2 hours. Those participants who are shown to have significant problems in prospective memory will be recruited to the intervention session. The intervention session will entail undergoing a treatment (experimental or placebo) followed by testing on the

JAAM and Removals task computer tests. This session will last between 2 and 2 ½ hours. Some adaptations may be made for participants with physical disabilities. Given the nature of their deficits, participants will receive letters detailing their appointment times. They will also receive a telephone or email reminder 24 hours prior these appointments. Participants will be invited to an NHS or voluntary organisation location for testing and intervention.

Recruitment to the study will occur by two routes.

(1) Participants may be recruited from a study running concurrently (Title: “Assessment of Everyday Executive Functioning in Individuals with Acquired Brain Injury”). This study uses identical assessment measures and methods to the present study (as described above). If participants demonstrate significant impairment with prospective memory following assessment in that study, they will be recruited to the present study at Point B in flowchart and would sign Consent Form B. Participants will already have signed a consent form with identical content to Consent Form A and would have received Participant Information Sheets A & B. Data from that study will be used for the present study. Participants will not repeat the assessment measures undertaken in the initial two assessment sessions. They will undertake an intervention, and be tested on the JAAM and Removals task computer tests.

(2) Should that study meet its sample size before the present study is completed, then participants will be recruited from clinician referral (point A in the flowchart) and would sign Consent Form A and B. This will involve all assessment measures described above, in addition to the potential involvement in the intervention and post-treatment assessments.

Those recruited by either route will receive Participant Information Sheets detailing the nature of both the assessment and intervention phases of the study. In either case they will sign Consent Form B. The attached flowchart details the full procedure.

Intervention

Consistent with Shallice & Burgess (1991) hypothesis of ‘strategy application disorder’, brief Goal Management Training will be undertaken initially with all participants to assist with the

ability to form intentions. This involves using a Stopping, Setting a Goal, Listing the Steps, and Learning the Steps, before continuing.

The experimental intervention will focus on the specific components influencing the successful recall of prospective cues: (1) Intention formation- this includes the use of imagery and errorless learning strategies to learn associations between target cues and desired actions. For example, visualising themselves immediately performing the action when they see the cue; (2) Event-based PM recall strategies. For example, manipulating the salience of the cue in terms of size, appearance and volume; (3) Time-based PM recall strategies. For example, using imagery to increase associations between cues and time-based objects and concepts (see Appendix 1 for a detailed description). To assist with generalisation, a variety of training tasks will be used, from well- to poorly-structured delayed intention problems.

The placebo intervention will faithfully employ GMT terminology and techniques, but will adopt a non-specific imagery training exercise used by Evans et al. (2006). This will involve using imagery to draw the first letter of the cue onto the face of a person that they know well. While this is found to improve name recall, it is not expected to improve intention realisation (see Appendix 2).

Justification of Sample size

GPower (v 3.1.2) (Faul et al., 2009) was used to calculate sample size. It is estimated that to detect a large effect size (Cohen's $f^2=0.35$), with $\alpha=0.05$, on the interaction of a within-between ANOVA, 20 participants with deficits in prospective memory will be required. This estimate is based on the finding of Kardiasmenos et al. (2008) who used a neurologically-impaired sample, adopted a implementation intention intervention and used a functionally-relevant outcome measure of PM, achieving a large effect size ($\eta^2=0.227$). However, as the present study uses a less directive training than Kardiasmenos et al., a more conservative sample estimate is appropriate should the obtained effect size be smaller. A sample of 26

participants will reduce the probability of the study being underpowered, and remains practical in the given timeframe.

Settings and Equipment

Where possible the participant will be tested in the base of the organisation from which they were recruited. In the absence of such premises, individuals will be tested in the Community Brain Injury Treatment Centre, Govan. Equipment required includes encrypted NHS laptops, software for VR programmes, neuropsychological assessments and record forms, and psychometric questionnaires (see appendix 3).

Data Analysis

2x2 mixed ANOVA will be applied to the data. Post hoc comparison in performance will be used to explore differential patterns of performance according to a predefined assessment profile of deficits.

Health and Safety Issues

Issues pertain to the use of participants who are (in varying degrees) impulsive, display irrational or unpredictable behaviour, and/or have poor emotional control. Clear guidelines on acceptable behaviour and conditions under which testing will be terminated will be devised. Testing will only occur in locations that have been risk assessed. Individuals who are intoxicated will be excluded from testing. Risks to participants include the use of a novel intervention, and stress associated with significant assessment. The use of blinding also risks introducing in participants a sense of failure or having been deceived. These are explored in detail in the appendices, although full debriefing will occur following the completion of testing. All participants will be informed in advance of the blinding and possibility of deception.

Ethical issues

Ethical issues relate to the use of vulnerable patient groups and application of a novel intervention within a research context. Blinding participants to their treatment allocation

also introducing ethical issues regarding potential deception of vulnerable individuals. Participants will have the opportunity to withdraw without any prejudice to their care. Due to NHS GG&C directives, encrypted laptops may be required to store and run datasets. Applications will be made for Site Specific approval, as participants may recruited for NHS GG&C and NHS Ayrshire & Arran.

Financial Issues

Sufficient funding will be necessary to cover the cost of record forms and questionnaires. Participants will not receive financial remuneration for participating. Details of expenses are included in the appendices (see Appendix 3).

.

Timetable

We aim to apply for ethical approval in September 2010 and to begin recruitment and investigation in autumn 2010 (see Appendix 4)

Practical Applications

This study aims to increase the number of evidence-based interventions for deficits in executive function by demonstrating the efficacy of implementation intentions in a brain injury population. Furthermore, it aims to provide further evidence of the separability of executive functions.

References

References can be found in Chapter 2 (Major Research Project).

2.9 Financial Costs

Item	No. required	Approximate Cost
<u>Questionnaires</u>		
Adapted DEX Questionnaires (carer & client)	40	Create own (2 sheets x 80 x £0.05 = £8.00)
PRMQ Questionnaire: client	40	Free to photocopy (£0.05 x 40 = £2.00)
PRMQ Questionnaire: carer	40	Free to photocopy (£0.05 x 40 = £2.00)
HADS Questionnaire	40	Free to photocopy (£0.05 x 40 = £2.00)
<u>Formal Recording Forms</u>		
Symbol Digit Modalities Test ¹	40	2 x pack of 25 (2 x £49.00 = £98.00)
CAMPROMPT Record Forms ¹	40	2 x pack of 25 (2 x £49.94 = £99.88)
<u>Constructed Recording Forms</u>		
WTAR Record Forms	40	Create own (P/C £0.05 x 40 = £2.00)
Matrix Reasoning subtest (WAIS-III)	40	Create own (P/C £0.05 x 40 = £2.00)
Modified six element test (BADs)	40	Create own (P/C £0.05 x 40 = £2.00)
Logical Memory subtest (WMS-III)	40	Create own (P/C £0.05 x 40 = £2.00)
Rey Complex Figure Test	40	Create own (P/C £0.05 x 40 = £2.00)
Tower-Test (D-KEFS)	40	Create own (P/C £0.05 x 40 = £2.00)
Demographic recording sheets & Computer Familiarity	40	Create own (P/C £0.05 x 40 = £2.00)
JAAM Scoring Sheet	40 (3 sheets)	Photocopying (£0.05 x 40 x 3 = £6.00)
<u>JAAM Materials</u>		
Re-usable documents	7 sheets	Printing (covered by paper costs)
Used task-specific documents	6 sheets x 40	Photocopying (£0.05 x 40 x 6 = £12.00)
<u>Information Packs</u>		
Printed Material	3 sheets x 60	Photocopying (£0.05 x 60 x 3 = £9.00)
Headed Paper	60 sheets	Printing (£0.16 x 60 = £9.60)
Envelopes (size C4)	60	3 x pack of 20 (3 x £1.30 = £3.90)
White Paper (500 sheets A4)	1 ream	£2.00
Consent Forms	40	Create own (P/C £0.05 x 40 = £2.00)
TOTAL COST		£270.38

This cost will be divided evenly between two experimenters.

3.0 Research Timetable

Date	MRP Progress/Tasks
April 2010	MRP Proposal submitted Costing form submission Completion of health and safety form
May – September 2010	MRP research supervision agreement Start research logbook Ethics approval Research & Development approval Site preparation Ordering materials and administration supplies
October 2010	Research Progress Meeting 1
October – December 2010	Start data collection
January – March 2011	Complete data collection Research Progress Meeting 2
April – May 2011	Complete data analyses Research Progress Meeting 3
June – July 2011	Submit drafts to supervisor
July 2011	Loose bind and submit
August 2011	Viva preparation
September 2011	Viva
September – November 2011	Submit corrections (if required)

3.1 Ethical and Research & Development Approval

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow
and Clyde
West of Scotland REC 5
Western Infirmary
Ground floor, Tennent Institute
38 Church Street
GLASGOW
G11 6NT

Telephone: 0141 211 2482
Facsimile: 0141 211 2811

08 October 2010

Mr Andrew Wood
Trainee Clinical Psychologist
NHS Greater Glasgow & Clyde
Section of Psychological Medicine,
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH

Dear Mr Wood

Study Title: Rehabilitation of Executive Function deficits following
Brain Injury: using Goal Management Training and
Implementation Intentions to improve Prospective
Memory.
REC reference number: 10/S1001/50

Thank you for your letter of 01 October 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The favourable opinion applies to the following Non-NHS research sites:

Research Site	Principal Investigator / Local Collaborator
The Brain Injury Rehabilitation Trust	Dr B O'Neill

Delivering better health

Headway Scotland	Ms G McCann
Momentum	Ms L Burke
Chest Heart and Stroke Scotland	Ms K Frew

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Investigator CV	1	25 August 2010
Protocol	2	25 August 2010
CV for Professor Jonathan Evans (Supervisor)	1	25 August 2010
Reminder letter for next routine clinical appointment	1	25 August 2010
First Appointment Letter	1.0	19 August 2010
Second Appointment Letter	1.0	19 August 2010
Neuropsychological assessment letter	1.0	30 August 2010
Appendix 1 Protocol for Goal Management (Experimental intervention)	1	25 August 2010
Advert leaflet	1.1	15 September 2010
REC application		31 August 2010
Covering Letter		30 August 2010
Questionnaire: Computer Familiarity	1.0	25 August 2010
Questionnaire: Prospective & retrospective memory (Carer)	1.0	25 August 2010
Questionnaire: Hospital Anxiety & Depression Scale	1.0	25 August 2010
Advertisement	2	August 2010
Advertisement	1.0	25 August 2010
Letter of invitation to participant	1.1	25 August 2010
GP/Consultant Information Sheets	1.0	09 August 2010
Participant Information Sheet	2.1	28 September 2010
Response to Request for Further Information		01 October 2010
Participant Information Sheet: B	2.1	29 August 2010

Participant Consent Form: A	1.1	28 September 2010
Participant Consent Form: B	1.0	25 August 2010
Questionnaire: Prospective & retrospective memory (Patient)	1.0	25 August 2010
Questionnaire: Modified Dysexecutive (Carer)	1.0	25 August 2010
Questionnaire: Goal Management	1.0	June 2009
Questionnaire: Goal Management (Carer)	1.0	25 August 2010
Clinical Recruiter Checklist	1	30 August 2010
Participant Screening Form	2.1	25 August 2010
Intervention Appointment Letter	1.0	25 August 2010
Clinical Team Letter Template	1.0	09 August 2010
Appendix 2 Protocol for Goal Management (Placebo intervention)	1	25 August 2010
Evidence of insurance or indemnity		09 August 2010

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/S1001/50	Please quote this number on all correspondence
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Yours sincerely



Dr Gregory Ofili
Chair

Coordinator/Administrator: Dr Erica Packard/Ms Elaine O'Donnell
Telephone Number: 0141 211 6208
E-Mail: erica.packard@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

R&D Management Office
Western Infirmary
Tennent Institute
1st Floor 38 Church Street
Glasgow, G11 6NT,

13 October 2010

Mr Andrew Wood
Trainee Clinical Psychologist
Dept of Psychological medicine
Gartnavel Royal Hospital
1055 Great Western Road
G12 0XH

NHS GG&C Board Approval

Dear Mr Wood,

Study Title:	Rehabilitation of Executive Function deficits following Brain Injury: using Goal Management Training and Implementation Intentions to improve Prospective Memory
Principal Investigator:	Mr Andrew Wood
GG&C HB site	Community Treatment Centre for Brain Injury
Sponsor	NHS Greater Glasgow & Clyde
R&D reference:	GN10NE339
REC reference:	10/S1001/50
Protocol no: (including version and date)	V2.0;25/08/10

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
 - a. During the life span of the study GGHB requires the following information relating to this site
 - i. Notification of any potential serious breaches.
 - ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

ivering better health

nhsggc.org.uk

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2. **For all studies** the following information is required during their lifespan.
- a. Recruitment Numbers on a quarterly basis
 - b. Any change of staff named on the original SSI form
 - c. Any amendments – Substantial or Non Substantial
 - d. Notification of Trial/study end including final recruitment figures
 - e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,



Dr Erica Packard
Research Co-ordinator

Cc NRSPCC