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University  
of Glasgow

Supporting Diabetes Self-management in Persons with Cognitive Impairment  
after Acquired Brain Injury  
AND  
Clinical Research Portfolio

**VOLUME I**  
**(Volume II bound separately)**

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Matriculation Number: 1103914  
August 2014

**Mental Health and Wellbeing**  
**College of Medical, Veterinary and Life Sciences**

*Submitted in part fulfilment of the requirements for the qualification of Doctorate in  
Clinical Psychology*

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## Chapter 1: Systematic Review

Cognitive Behavioural Therapy for Functional Neurological Symptoms: A Systematic Review

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Prepared in accordance with guidelines for submission to *Journal of Neurology*  
(Appendix 1.1)

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***Submitted in part fulfilment of the requirements for the qualification of Doctorate in  
Clinical Psychology***

## **Abstract**

*Background:* Functional Neurological Symptoms (FNS) refer to symptoms that resemble those of neurological conditions (e.g. seizures, limb paralysis/weakness, dizziness) but have no associated organic cause. Cognitive behaviour therapy (CBT) may be an effective intervention for individuals with FNS. This study systematically reviews the evidence regarding the effectiveness of this intervention and examines the methodological quality of the research in this area.

*Method:* Four databases were searched electronically, yielding six papers that met inclusion and exclusion criteria. The reference lists of these included papers were then hand searched for further relevant articles resulting in the addition of two further relevant papers. The methodological quality of these eight papers was assessed using the Clinical Trials Assessment Measure [1] and effect sizes were calculated.

*Results:* Two studies employed Randomised Controlled Trial (RCT) methodology; the remaining studies were pre-post trials. Only one of the included studies reached the cut-off for adequate methodological quality suggested by Wykes and colleagues [2]. All studies except for one found significant benefits of CBT for FNS and effect sizes were medium to large.

*Conclusion:* There is preliminary evidence suggesting that CBT may be a useful intervention for FNS. RCTs are difficult to conduct with this population and future research should attempt to utilise other suitable research designs, for example Single Case Experimental Designs (SCEDs). Further studies of high methodological quality are needed.

**Keywords:** Functional Neurological Symptoms, Conversion Disorder, Cognitive Behaviour Therapy, Systematic Review

## Introduction

Functional neurological symptoms (FNS) refer to symptoms that resemble those of neurological conditions but have no associated organic cause. Examples include limb weakness, movement disorders, seizures and blackouts. FNS have been known by many different labels including medically unexplained symptoms, conversion disorder, dissociative disorder and psychosomatic disorder. For the purposes of this review we will refer to these disorders as 'functional' as research has shown that this label is the most acceptable to patients [3]. DSM-5 refers to these conditions as 'conversion disorders' and defines them as 'one or more symptoms or deficits affecting voluntary motor or sensory function that suggest a neurological or other general medical condition' [4]. They further specify that psychological factors play a role in the onset or maintenance of these symptoms.

The Scottish Neurological Symptoms Study [5], a multi-centre prospective cohort study of 3781 first attendance neurology outpatients found that 30% had symptoms that were either 'not at all' or only 'somewhat' explained by neurological disease indicating that FNS are a prevalent problem. The study also found that these patients had similar levels of physical impairment to those whose symptoms had an organic cause but that they tended to have higher rates of distress. Twenty seven percent of FNS patients in the study were not in employment due to health reasons, compared with nineteen percent of those with organic symptoms. These figures suggest that FNS have a high economic impact as well as causing significant disability to individuals.

It has been widely suggested that psychological factors may play a significant role in the development and maintenance of FNS. It has been found that the number of psychological symptoms reported by individuals with functional somatic symptoms may correlate with the number of functional symptoms reported [6]. Patients with FNS have been shown to display higher rates of emotional distress when compared to those with neurological disease [5]. There is also evidence that aversive experiences in childhood are more common in these patients [7]. Functional neurological symptoms may be maintained by a combination of cognitive, behavioural, emotional and physiological factors, for example catastrophic cognitive interpretations of bodily events, avoidance/safety behaviours and mood [8]. Cognitive Behavioural Therapy (CBT) has been shown to be an effective treatment for other somatoform disorders [9 - 12]. It follows that psychological treatments such as CBT may be effective in treating these disorders.



A number of review articles of CBT for conversion disorders have been published to date. Allen and Woodfolk conducted a review of the literature on CBT for somatoform disorders, including conversion disorder/functional neurological symptoms [13]. This review did not identify any controlled trials of CBT for this population. Hopp & LaFrance conducted a review of CBT specifically for FNS [14]. The study reviewed a number of articles relating to CBT for non-epileptic seizures (NES). One case report of CBT for functional movement disorder was also reviewed but no articles were found relating to CBT for other FNS. This review did not assess the methodological quality of included studies. The authors concluded that further controlled treatment trials were needed to determine efficacy. To our knowledge there has not been an attempt to date to systematically review and evaluate the methodological quality of the literature relating to CBT for the treatment of functional neurological disorders.

### *Aims*

This systematic review aims to investigate the efficacy of CBT for FNS and to formally evaluate the methodological quality of the literature in this area.

## **Methods**

### *Search Procedures*

An electronic search of Medline, Embase, Web of Science and PsycINFO databases was conducted on 17/05/14.

The following search terms were utilised:

Cognitive behav\* OR CBT OR psychological intervention\* OR psychological therap\*

AND

Mesh term (conversion disorder), Keywords (conversion disorder\* OR conversion symptom\* OR medically unexplained symptom\* OR functional disorder\* OR functional symptom\* OR functional neurolog\* disorder\* OR functional neurolog\* symptom\* OR somat\* disorder\* OR somat\* symptom\* OR psychosomat\* disorder\* OR psychosomat\* symptom\* OR dissociat\* disorder\* OR dissociat\* symptom\* OR psychogenic disorder\* OR psychogenic symptom\* OR non-organic disorder\* OR non-organic symptom\*)

(\* denotes truncation command to identify all possible endings of the word).

## *Selection Criteria*

### *Inclusion Criteria*

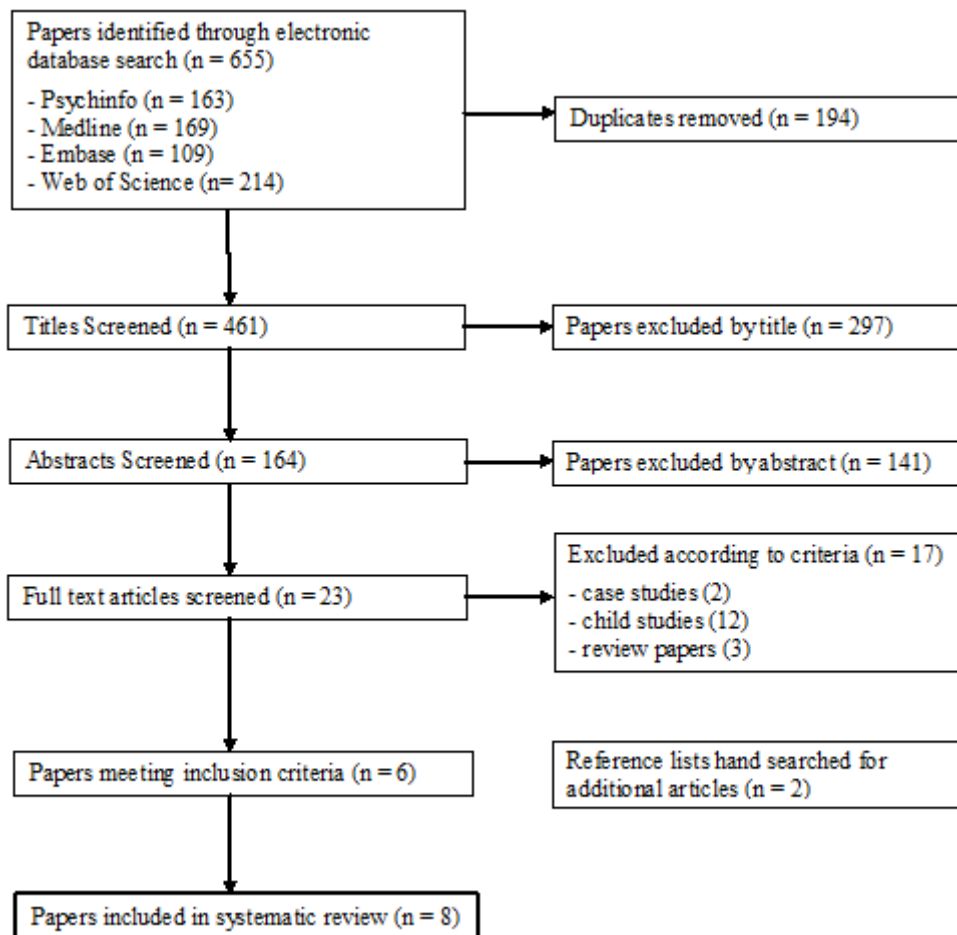
- Randomised controlled studies, pre-post studies, single case experimental design studies.
- Adult male or female, 18 years of age or older with any type of functional (non-organic) neurological disorder.
- Studies investigating the efficacy of an individual or group intervention of CBT for this population.
- Studies published in English

### *Exclusion Criteria*

- Single case studies
- Books/book chapters
- Review Studies
- Commentaries

## *Sample Description*

The results of the search process are illustrated in Figure 1 below. A search of Medline, Embase, PsycINFO and Web of Science databases yielded 655 references. Search results from each database were transferred to Refworks referencing software. Following the removal of duplicates 461 studies remained. The titles of the remaining studies were screened resulting in a further 297 irrelevant papers being removed. The abstracts of the remaining 164 articles were reviewed and studies that clearly did not meet the inclusion/exclusion criteria were removed. The full texts of the remaining 23 articles were reviewed leaving 6 articles that met the criteria [15 - 20]. Two of these articles [19, 20] reported on different follow-up periods of the same study. The reference lists of these 6 remaining papers were hand searched leading to the inclusion of a further two studies [21, 22]. The final review included eight articles relating to seven studies.



**Figure 1** Flow Diagram Illustrating Search Process

### *Quality Rating*

The methodological rigour of each study was evaluated using the Clinical Trials Assessment Measure (CTAM) [1]. This is an assessment tool designed for assessing the quality of trials of psychological treatments in mental health. It consists of fifteen items grouped into six areas: sample (10 points); allocation to treatment (16 points); outcome assessment (32 points); control groups (16 points); analysis (15 points); and description/quality of treatments (11 points). The measure has a maximum possible score of one hundred (see Appendix 1.2). The scale has adequate internal consistency, excellent concurrent validity and good blind inter-rater agreement [2]. The CTAM was selected for use in this review due to its good psychometric properties, brevity and ease of use and the fact that it has been specifically designed for assessing trials of psychological treatments such as CBT.

Two reviewers rated all included studies in order to assess inter-rater reliability. Agreement between the reviewers was high (91%) and any discrepancies were resolved

through discussion. Scores on the CTAM varied, with a mean of 38.00 ( $SD = 20.60$ ) and a median of 31 (range = 10–68). Wykes and colleagues suggested that a total CTAM score of 65 or higher would indicate adequate methodological quality, however the validity of this cut-off is yet to be investigated [2].

## **Results**

Each article is summarised in terms of the type of functional disorder examined, the design of the study, the number and characteristics of subjects and control subjects, interventions, outcomes evaluated and quality (see Table 1).

**Table 1** Description and Quality Rating of Included Studies

Study	CTAM Rating	Design	Subjects	Controls	Intervention	Outcome Measures	Conclusions	Effect Sizes
<b>Non-epileptic seizures</b>								
Goldstein et al., [21]	26	Non-controlled pre-post study. 6 month follow-up	N = 20, 16 received treatment M=2, F=14 average age 34.9±13.4	n/a	12 individual CBT sessions (14 hours total duration). Weekly/Fortnightly	<i>Primary:</i> Seizure frequency FQ WSAS HADS Employment Status <i>Secondary Measures:</i> MHLC IPQ	Intention to treat analysis: Post-treatment: significant reduction in seizure frequency 6-month follow-up: 25% seizure free	<b>Seizure frequency Pre vs. Post treatment (r = -.61)</b> <b>Post-treatment vs. 6-month follow-up (r = -.11)</b>
Goldstein et al., [17]	68	RCT, 6 month follow-up	N = 33, M=9, F=24 Age 37.4 ± 12.6	N = 31, M=7, F=26 Age 35.9 ± 15.1	CBT (12 one hour sessions) and standard medical care vs. Standard medical care only	Monthly seizure frequency Seizure freedom WSAS HADS Modified CSRI	CBT group significantly lower seizure frequency at treatment end.  Trend towards lower seizure frequency in CBT group at follow-up.	Seizure frequency Intervention vs. Control at end of treatment (d = .75) Intervention vs. Control at 6-month follow-up (d = .42)
LaFrance et al., [15]	25	Non-controlled pre-post study. 12 month follow-up	N = 21, 20 analysed, M=4, F=17, average age 36.0	n/a	CBT (12 one hour sessions)	Patient recorded seizure diary BDI MHRSD DTS DES BIS FAD SCL-90 GAF OHS LIFE-RIFT WoC QOLIE	Significant reduction in weekly seizure frequency post treatment	<b>Seizure frequency pre vs. post treatment (r = .66)</b>

Study	CTAM Rating	Design	Subjects	Controls	Intervention	Outcome Measures	Conclusions	Effect Sizes
<b>Non-epileptic seizures continued...</b>								
Kuyk et al., [22]	10	Non-controlled pre-post study with 6 month follow up	N=29, 26 received treatment, 4 patients with a co-morbid diagnosis of epilepsy were excluded from analysis, follow-up n=16	n/a	Inpatient multidisciplinary treatment based on CBT principles	Seizure frequency SCL-90 BDI STAI UCL SF-36 DISQ	Significant reduction in seizure frequency post treatment and a further significant reduction from end of treatment to follow-up	<b>Seizure frequency Pre vs. Post treatment (r = -.35) Post-treatment vs. 6-month follow-up (r = -.35)</b>
Conwill et al., [16]	31	Pre-post group study	N = 16 (NES=10, other FNS=6), M=4, F=12, average age 37.4±11.9	n/a	CBT-based group therapy. NES - 4 sessions, other FNSs – 5 sessions both 1 hour duration, weekly	Monthly attack frequency SF-36 HADS CGI Neuropsychiatric assessment	Outcomes NES patients only; no significant differences on any outcome measures	<b>No significant differences found post intervention therefore no effect sizes were calculated</b>

Study	CTAM Rating	Design	Subjects	Controls	Intervention	Outcome Measures	Conclusions	Effect Sizes
<b>Functional Dizziness</b>								
Edelman et al., [19] & Mahoney et al., [20] – follow-up paper	58	RCT 1 and 6 month follow-up	N = 20 M=11, F=30, average age 46.78±12.65  Follow-up paper: N = 23 M=12, F=32, average age 46.7±12.97	N = 21, wait-list	3 individual CBT sessions, wait-list received intervention 4 weeks later	MINI DHI DSI SBI DASS-21	Significant reductions on the DHI, DSI & SBI but no significant change on DASS-21 at post treatment  Improvements made post-treatment were maintained at 6-month follow-up	Treatment Group: DHI (d = 1.38) DSI (d = 1.17) SBI (d = 1.58) Waitlist Group (post treatment): DHI (d = 1.02) DSI (d = 0.98) SBI (d = 1.34)  Baseline vs. 6-mth follow-up: Treatment Group DHI (d = 1.36) DSI (d = 1.18) SBI (d = 1.51) Waitlist Group DHI (d = 1.01) DSI (d = 0.88) SBI (d = 1.39)
<b>Functional Dysphonia</b>								
Daniilidou et al., [18]	48	Pre-post consecutive cohort controlled study. Voice therapy vs. CBT enhanced voice therapy. Multiple t-tests	N = 16, outcome data for 13	N = 16, outcome data for 15	6 individual one hour weekly sessions of voice therapy/CBT enhanced voice therapy.	GRBAS VPQ VoiSS HADS GHQ-28	Control group improved significantly on VPQ, VoiSS & GHQ-28  CBT group improved significantly on all measures and improved significantly more than controls on GHQ-28	Control group: VPQ (d = -1.5)* VoiSS (d = -.9)* GHQ-28 (d = -.6)* CBT Group: GRBAS (d = -1.4)* VPQ (d = -1.8)* VoiSS (d = -1.4)* HADS anx (d = -.4)* HADS dep (d = -.6)* GHQ-28 (d = -.9)*

**Bold typeface indicates effect sizes were calculated by the first author of this review**

*Abbreviations:*

BDI	- Beck depression inventory [23]
BIS	- Barrett Impulsivity Scale [24]
CGI	- The Clinical Global Impression Scale [25]
CSRI	- Client Service Receipt Inventory [26]
CTAM	- Clinical Trials Assessment Measure [1]
DASS-21	- Depression, Anxiety and Stress Scales 21 [27]
DES	- Dissociative Experiences Scale [28]
DHI	- Dizziness Handicap Inventory [29]
DISQ	- Dissociation Questionnaire [30]
DSI	- Dizziness Symptom Inventory [31]
DTS	- Davidson Trauma Scale [32]
FAD	- Family Assessment Device [33]
FQ	- Fear Questionnaire [34]
GAF	- Global Assessment of Functioning [35]
GHQ-28	- General health Questionnaire 28 [36]
GRBAS	- Grade, Roughness, Breathiness, Asthenia, Strain Scale [37]
HADS	- Hospital Anxiety and Depression Scale [38]
IPQ	- Illness Perception Questionnaire [39]
LIFE-RIFT	- Longitudinal Interval Follow-UP Evaluation Range of Impaired Functioning [40]
MHLC	- Multidimensional Health Locus of Control Scale [41]
MHRSD	- The Modified Hamilton Rating Scale for Depression [42]
MINI	- Mini International Neuropsychiatric Interview [43]
OHS	- Oxford handicapped Scale [44]
SBI	- Safety Behaviour Inventory [45]
SCL-90	- Symptom Checklist-90 [46]
SF-36	- 36-item Short Form Health Survey [47]
STAI	- State-Trait Anxiety Inventory [48]
UCL	- Utrecht Coping List [49]
QOLIE	- Quality of life in epilepsy [50]
VoiSS	- Voice Symptoms Scale [51]
VPQ	- Voice Performance Questionnaire [52]
WoC	- Ways of Coping [53]
WSAS	- Work and Social Adjustment Scale [54]



### *Data Synthesis*

Due to the heterogeneity of included studies in relation to disorders treated, characteristics of the interventions, outcomes measured and methods of analysis utilised, meta-analysis of the results was considered to be inappropriate. Narrative synthesis of the included studies was therefore completed.

### *Non-Epileptic Seizures*

The term non-epileptic seizures (NES) is used to refer to events which greatly resemble epileptic seizures in appearance but are not accompanied by changes in electrical activity in the brain which characterise epilepsy. They are among the most common type of FNS [55]. Antiepileptic medications are not an effective treatment for these individuals; therefore the focus for treatment has turned to psychological interventions with a small number of trials of CBT for NES being carried out in recent years.

Goldstein and colleagues [21] employed a non-randomised, pre-post design to evaluate the effect of CBT (12 sessions delivered by a CBT trained nurse therapist following a detailed treatment protocol) on seizure frequency and psychosocial functioning both at end of treatment and at six month follow up. Monthly seizure frequency and anxiety and depression (measured using the HADS) were significantly reduced post-treatment and these gains were maintained at six month follow up. The intervention was well described and employed a manual however there was no assessment of protocol adherence or treatment quality. The analysis employed was appropriate and included all randomised participants. The dropout rate was 20% and comparisons were performed between completers and non completers indicating no significant differences.

The study received a CTAM rating of 26 out of 100 indicating that methodological rigour was below the level considered to be adequate by Wykes and colleagues [2]. The study did not employ a control group. Assessments were not carried out by independent assessors blinded to treatment condition; therefore this may have biased the results. The study had a small sample size (n=16) and did not report a power calculation. However the researchers found a significant difference in seizure frequency post-treatment compared to baseline with a large effect.

Kuyk and colleagues [22] evaluated a non-randomised uncontrolled study of a multidisciplinary inpatient treatment based on cognitive behavioural principles with six month follow up. The authors report a significant decrease in seizure frequency at end of

treatment and follow up, however the study suffered a number of methodological issues. The sample size was relatively small (n=29), including three drop outs and four exclusions due to a co-morbid diagnosis of epilepsy. A further six individuals were lost to follow up. There was no investigation of dropouts and they were not included on the analysis. The description of the intervention was insufficient and this was not manualised. Finally assessments were not carried out by independent assessors. The CTAM score for this study was 10 out of 100 suggesting poor methodological rigour. The study reports significant reductions in seizure frequency post-treatment and at six month follow-up and effect sizes at both time points were of medium strength.

LaFrance and colleagues [15] again evaluated the effectiveness of CBT (12 weekly sessions) for reducing NES frequency through a non-randomised pre-post study. Seizures reduced significantly at end of treatment and significant improvements were found in quality of life, family functioning and psychosocial functioning. Sessions were administered according to a protocol by an experienced CBT practitioner and the quality of the intervention and adherence to the protocol were monitored through audio recordings. One of the inclusion criteria of the study required the diagnosis of NES to have been established through video EEG monitoring which resulted in 79% of screened participants being excluded. This may limit the generalisability of the results to clinical practice. The sample size was small (n=21) with a 19% attrition rate (n=17) and was not based on a power calculation. Drop outs were investigated and all but one of the original twenty one participants were included in a partial intention to treat analysis (one was excluded as they only completed baseline measures). Assessments were not carried out by independent assessors and this may have introduced bias. The study received a CTAM score of 25 out of 100 which is below the cut-off suggested by Wykes and colleagues [2] for adequate methodological quality. Effect sizes however, were large.

Conwill and colleagues [16] conducted the first efficacy study of a CBT-based group therapy for NES (n=10) and other FNS (6). When looking at the results for NES patients individually the study failed to find any significant benefit of CBT for seizure reduction. The CTAM rating for the study was 31 out of 100 suggesting that the methodological rigour was below an adequate level. The study was uncontrolled and there was no randomisation. Standardised measures were used to evaluate the intervention and the treatment was adequately described with adherence monitored, although it was not clear whether a treatment protocol was followed. Goldstein and colleagues [17] conducted the only

randomised controlled trial (RCT) on this population to date, comparing CBT against standard medical care (SMC) with six month follow up data. Seizure frequency was significantly reduced in the CBT group versus the SMC group at the end of treatment and there was a trend towards the superiority of the CBT intervention at six month follow up. No significant differences were found between the groups on depression or anxiety as measured by the HADS [38]. This was a well designed study with a reasonable sample size (SMC=31, CBT=33). Randomisation was carried out independent of the research team, analysis of results was appropriate and intention to treat analysis was performed. The treatment was described in detail and followed a protocol and CBT quality and therapeutic alliance was assessed. This study was the only included study rated as having adequate methodological quality as defined by Wykes and colleagues [2]. Effect sizes for the CBT intervention showed a medium to large effect post treatment and a medium effect at six month follow up.

#### *Functional Voice Disorders*

Functional voice disorder refers to a difficulty in speaking which usually manifests itself through hoarseness in the absence of a physical cause. Research in the area has shown that this group of individuals tend to have poorer psychological functioning than those with an organic cause. Willinger and colleagues [56] found that patients with functional dysphonia had significantly higher scores than controls on self-reported symptoms of depression, anxiety and health anxiety and suggested that these symptoms should be addressed when working with these patients. Baker [57] investigated the psychological factors that contribute to the development of functional voice disorders and identified that these individuals tend to have higher levels of anxiety, depression and have problems processing/expressing negative emotions. Butcher and colleagues [58-61] have strongly advocated the use of CBT integrated with traditional voice therapy by Speech and Language Therapists in the management of functional voice disorders in order to improve both voice quality and psychological wellbeing. Despite this, few treatment studies utilising CBT for this population have been undertaken.

Only one published pilot study was identified that compared conventional voice therapy with 'CBT-enhanced' voice therapy in a nonrandomised consecutive cohort design [18]. The authors compared participants receiving conventional voice therapy to those receiving conventional voice therapy with the addition of CBT. Both groups showed

significant improvements on the GHQ-28 with the CBT enhanced group also showing significant improvement on the HADS [38]. The CBT group scored significantly higher than controls on the GHQ-28 [36] following intervention suggesting that CBT provided benefits for the well being of participants that conventional voice therapy alone did not. These results however should be interpreted with caution. Multiple t-tests were performed on the data with no correction made for multiple comparisons thus increasing the likelihood of Type 1 error (finding a significant difference where none exists).

This study received a CTAM rating of 48 out of 100 indicating reasonable methodological quality. Effect sizes were large for all voice quality outcome measures and medium effect sizes were found for depression and anxiety.

### *Functional Dizziness*

Functional dizziness refers to cases where dizziness has no physical cause or where there is a physical cause for dizziness but this is maintained or exacerbated by anxiety. Research has found links between dizziness and anxiety disorders in many individuals [10, 62]. Traditional treatment for dizziness has traditionally consisted of vestibular rehabilitation (VR) which utilises a range of exercises to promote central nervous system compensation for vestibular deficits. This treatment however may be of limited use for patients whose dizziness is primarily attributable to anxiety. A number of studies have investigated a combination of VR and CBT for treating these patients. Johanson and colleagues [63] conducted a randomised study of vestibular rehabilitation combined with elements of CBT compared to a wait-list control group in an older adult population. Numbers were small but significant improvements were noted on the DHI [29]. No changes were found on symptoms of vertigo or symptoms of anxiety and depression. Andersson and colleagues [64] conducted a similar study again investigating the benefit of vestibular rehabilitation combined with elements of CBT to a waitlist control group for a younger adult population. Again improvements were seen on the DHI [29] and the intervention was also found to reduce distress compared with controls. These studies provide some indication that CBT may be a useful intervention for this disorder however CBT was not the main intervention of these studies and its relative contribution could not be identified; therefore these studies were not included in this review.

One study on CBT for functional dizziness and one additional paper that provided follow-up data for this study met inclusion and exclusion criteria and were included in this

review. Edelman and colleagues randomised forty-one patients with functional dizziness to intervention (three sessions of CBT based on the model of panic disorder delivered by a clinical psychologist) or a waitlist control group [19]. Significant differences were found for both groups between pre-treatment and post-treatment on the DHI [29] and two author created, non-validated measures assessing severity of dizziness symptoms and frequency of safety behaviours, with the intervention group showing greater improvement than controls on all measures. Effect sizes comparing pre-treatment to post-treatment scores on dizziness measures were large. They also reported significant differences between the post-waitlist and post-treatment scores for the two groups on these three measures. No significant differences were found in levels of depression, anxiety and stress as measured by the DASS-21 [27] when comparing pre and post-treatment scores or post-waitlist and post-treatment scores. The intervention was brief providing only three sessions of CBT which is less than would generally be required to see a benefit when treating other disorders such as depression, anxiety, panic etc. It is possible that this may have accounted for the lack of significant improvement on DASS-21 scores.

The study received a CTAM rating of 58 out of 100, indicating reasonable methodological rigour. There were however a number of limitations; assessments were not carried out by independent assessors blinded to treatment condition; therefore this may have biased the results. The study had a relatively small sample size (treatment  $n = 20$ , control  $n = 21$ ) which also may have impacted the ability to detect meaningful change on measures of anxiety and depression following intervention. The use of a waitlist control group rather than a no treatment or treatment as usual control group may have been problematic in this study. It is possible that the use of wait list control group could introduce bias as the anticipation of intervention could itself lead to improvement. Participants in the waitlist control group in this study appear to have made improvements on dizziness and mood measures without having been administered the intervention making it difficult to detect change due to the intervention. A no treatment or treatment as usual control group may therefore have strengthened the design of the study. The authors subsequently published a follow up paper reporting outcomes at one and six month follow-up for the intervention group [20]. Results suggested that gains were maintained at both follow up periods again with large effect sizes found for improvements on dizziness measures.

### *Other FNS*

It is possible that CBT may be efficacious in the treatment of other functional neurological disorders such as functional movement disorder or functional paralysis; however our search revealed no studies of sufficient quality to allow inclusion in this review.

### **Discussion**

Functional neurological symptoms are a prevalent problem causing widespread disability with significant costs to the individuals and wider society. While a recent review by Hopp and LaFrance [14] made a valuable contribution to the area by describing the different types of FNSs and summarising the literature in this area, there was no formal assessment of the methodological quality of the included studies. The current study attempts to build on this by utilising a methodological quality assessment measure to provide information on the strength of the evidence for CBT as a treatment for these disorders. The present study further builds on the review of Hopp and LaFrance [14] by including additional studies that have been published since this article relating to functional voice disorders [19, 20] and functional dizziness [18].

Five studies investigating CBT for NES were reviewed [15-17, 21, 22]. One study with adequate methodological quality found significant benefits of CBT for seizure reduction with a medium to large effect post treatment and a medium effect at six month follow up. The other four studies that were included for this condition were all rated as having inadequate methodological rigour and all had small sample sizes. Three of these studies found a significant reduction in seizure frequency post-treatment, of these two reported large effect sizes and one reported a medium to large effect size [15, 22, 17]. One study of a group intervention did not find any significant benefit of CBT for reducing seizure frequency [16]. In summary there is some evidence that CBT may be an effective intervention for reducing seizure frequency in NES, however these results should be replicated in studies with higher methodological rigour. There is currently no evidence for the effectiveness of CBT group interventions for NES.

Two papers on functional dizziness relating to different follow-up periods of the same study were reviewed [19, 20]. The study was an RCT of reasonable methodological quality that found a significant reduction in dizziness at post-treatment and six month follow-up with large effect sizes. This suggests that even brief CBT may be a useful intervention for functional dizziness. Further high quality randomised studies utilising

validated outcome measures and assessor blinding may be warranted to further investigate the potential benefits of CBT for this population.

Lastly the included paper relating to CBT for functional voice disorder found Voice Therapy and CBT-enhanced Voice Therapy had equivalent benefits in relation to improvements on voice scales [18]. The CBT-enhanced group also made significant benefits on a measure of general health. This study however suffered from some methodological limitations. It is as yet unclear what additional benefits CBT may confer above traditional voice therapy for this population and further studies of high methodological quality are needed.

Similar to the findings of Hopp and LaFrance [14], the results of this review suggest that there is as yet limited evidence to suggest that CBT is an effective intervention for FNS. The current review built on the findings of Hopp and LaFrance [14] by assessing the quality of the literature in this area. Findings suggest that there were a number of key methodological limitations of the studies included in this review. Very few studies employed independent assessors blinded to treatment group allocation for evaluating outcomes. While most studies employed a treatment manual/protocol, few assessed adherence to the protocol or treatment quality. The majority of studies included in this review were pre-post studies with only two studies utilising a Randomised Controlled Trial (RCT) design and many studies had small sample sizes. Only one study included in the review [17] met the CTAM cut-off suggested by Wykes and colleagues [2] for adequate methodological quality. This suggests that improvements are needed in the quality of research in the area.

While RCTs may be seen as the gold standard evaluation studies, these may not be the most practical for this population. RCTs are time-consuming and the costs of conducting them are high, they can be narrow in scope and lack generalisability to problems encountered in everyday clinical practice and require large sample sizes for randomisation and adequate power which may not be practically achievable. Furthermore RCTs require patients to be randomised to either a control or intervention condition, in some cases it may be ethically inappropriate to withhold treatment, therefore quasi-experimental designs where participants act as their own controls may be more suitable. Given the paucity of research in this area reflecting the difficulties of conducting RCTs with this population, it may be necessary to consider other types of methodology for conducting research in this area.

Barnett and colleagues [65] have suggested that Single Case Experimental Designs (SCEDs) may be better suited to studies where the aim is to understand and change patient functioning and targeted sample sizes are less than 30. At this preliminary stage in investigating the potential of CBT for these disorders, SCEDs may be useful for investigating the amount, intensity and type of intervention needed to improve patient outcomes. Guidelines for evaluating the methodological quality of these studies and recommendations on how data can be analysed are available [66-68]. As such SCEDs may present a viable alternative to RCTs for investigations of the efficacy and effectiveness of CBT for FNS.

While the research considered in this review provides some preliminary evidence for the benefit of CBT interventions for FNS, further attention needs to be given to what elements of CBT may be effective for this population, whether standard CBT needs to be tailored to the needs of this population and how many sessions may be needed in order for improvements to be achieved.

Currently service provision for these individuals is patchy with no defined treatment pathways. Service provision, treatment guidelines and pathways and staff training cannot be developed for these conditions until we have evidence indicating what treatments are effective; therefore studies that are well designed and of high methodological quality are urgently needed.



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## Chapter 2: Major Research Project

Supporting Diabetes Self-Management in Persons with Cognitive Impairment after Acquired  
Brain Injury

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***Submitted in part fulfilment of the requirements for the qualification of Doctorate in  
Clinical Psychology***

## **Plain English Summary**

Individuals with cognitive impairment arising from acquired brain injury (ABI) are often supported to engage in diabetes self-management through the use of verbal guidance provided by carers. While this can be effective, it may not always be acceptable to individuals who may feel upset and embarrassment as a result of a loss of independence and this may in turn lead to emotional strain on carers. Furthermore the costs of providing this level of personal support are not insignificant. The use of an automated verbal prompting system may hence reduce carer burden and provide a more acceptable intervention for individuals.

Guide was developed by O'Neill and Gillespie (2008) as an assistive technology for cognition (ATC) that aims to replicate the verbal guidance often provided to individuals with cognitive impairment by carers. The system prompts users, asks questions of them and accepts verbal responses ('yes' and 'no'). Guide has previously been shown to be effective in supporting individuals with cognitive impairment to put on their prosthetic limbs (O'Neill, Moran & Gillespie, 2010) and to complete their morning routine involving getting out of bed and completing personal care (O'Neill, Best, Gillespie & O'Neill, 2013).

The aim of this study is to investigate whether Guide can assist individuals with cognitive impairment to self-manage their diabetes. Two participants undergoing rehabilitation in a specialist brain injury rehabilitation unit with a diagnosis of diabetes and ABI took part in the study. These participants were not able to manage their diabetes independently because of their ABI. Participants completed a number of baseline sessions where they were prompted through the task by staff. They then completed a number of sessions where prompting was provided by Guide after which they completed further sessions where staff provided prompts. All sessions were video recorded to allow them to be scored.

Results of the study showed that participants benefited from using the Guide. When using Guide they needed less prompting from staff. Participant 1 made fewer errors and participant 2 was able to complete more of the steps of the task without any help when compared to the baseline phase where staff provided prompts.

The practical applications of Guide are potentially wide. It is possible that Guide could be used to support people with cognitive impairment due to other causes, for example dementia or learning difficulties. It could also be used to support other complex behaviours that are usually verbally prompted by carers.



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## **Supporting Diabetes Self-Management in Persons with Cognitive Impairment after Acquired Brain Injury**

**Background.** Individuals with cognitive impairment arising from acquired brain injury (ABI) are often supported to engage in diabetes self-management through verbal guidance provided by carers. Guide, developed by O'Neill and Gillespie (2008), is an automated verbal prompting system which aims to replicate the verbal guidance often provided to individuals with cognitive impairment by carers.

**Aims.** The aim of this study is to investigate whether Guide can improve the ability of individuals with cognitive impairment to self-manage their diabetes.

**Methods.** Participants were two individuals recruited from a specialist brain injury rehabilitation unit who had a diagnosis of diabetes and ABI. The study employed an ABA design using multiple baseline across participants Single Case Experimental Design (SCED) methodology.

**Results.** Results indicated that the use of Guide significantly reduced the level of staff prompting needed for task completion when compared to baseline for both participants. For participant 1, use of Guide reduced the number of errors made during task performance and for participant 2 it increased the proportion of the task that was sequenced correctly.

**Applications.** It is possible that Guide could be used more widely to support individuals with cognitive impairment (e.g. dementia, learning disability) and to support other complex behavioural sequences.

**Keywords:** acquired brain injury, assistive technology for cognition, executive function, rehabilitation

## **Introduction**

Many chronic medical conditions exist that require individuals to engage in medical self-management in order to regulate them. Diabetes mellitus is one such condition which requires sufferers to self monitor their blood glucose levels and use this information to guide their behaviour with regard to food and liquid intake, exercise and insulin administration. The cognitive burden of engaging in blood glucose monitoring and planning future action can therefore be high, requiring the individual to engage in complex sequencing behaviours.

Diabetes mellitus is often co-morbid with other conditions which can impair cognition including vascular related cognitive impairment, mild cognitive impairment, traumatic brain injury and hypoglycaemic brain injury (Biessels, Staekenborg, Brunner, Brayne, & Scheltens, 2006; Draelos, Jacobson, Weinger, Widom, Ryan, Finkelstein & Simonson, 1995; Luchsinger, Reitz, Patel, Tang, Manly & Mayeux, 2007). Individuals with these conditions often require a high degree of personal support in order to engage in diabetes self-management and the costs of providing this level of support are not insignificant.

Individuals with cognitive impairment arising from acquired brain injury (ABI) are often supported to engage in diabetes self-management through the use of scaffolding which refers to a process of providing verbal guidance during task performance (Sawyer, 2006). Scaffolding has been shown to be effective in reducing errors when learning a new skill when compared to supervised trial and error learning in a sample of individuals with cognitive impairment (Donaghey, McMillan & O'Neill, 2010). Although carer scaffolding can be effective, it may not always be an acceptable intervention to individuals with cognitive impairment who may feel upset and embarrassment as a result of a loss of independence which may in turn lead to emotional strain on carers. The use of an automated verbal scaffolding system may hence reduce carer burden and provide a more acceptable intervention for individuals.

Guide (General User Interface for Disorders of Execution) is an automated verbal prompting system that was developed by O'Neill and Gillespie (2008) as an assistive technology for cognition (ATC) and which aims to imitate the verbal guidance often provided to individuals with cognitive impairment by carers. The system prompts users, asks questions of users and accepts verbal responses ('yes' and 'no'). The system sequences complex tasks for users into steps and sub steps and asks a series of questions for each. In

this manner a user can be guided through a complex behavioural sequence in a manner which simulates carer scaffolding of task performance.

Errorless learning has been defined as 'a learning condition that involves the minimisation of errors during the learning process' (Clare & Jones, 2008; p. 1). The concept was first applied to individuals with memory impairment arising from acquired brain injury by Baddeley & Wilson (1994). They suggested that for people with memory impairment it may be important to restrict errors that occur during the learning process as priming and implicit memory may mean that once a mistake has been made, individuals with cognitive impairment may be more likely to make the same mistake again. They suggested that errorless learning may facilitate performance to a greater degree than trial and error methods in populations suffering cognitive impairment. Errorless learning principles have previously been applied in rehabilitation to practical tasks with success (Baddeley & Wilson, 1994; Clare et al., 2001). Guide can be conceptualised as an errorless learning approach as it prompts users before each action step thus minimising errors.

Guide has previously been shown to be effective in supporting individuals with cognitive impairment to don their prosthetic limbs (O'Neill, Moran & Gillespie, 2010). Use of Guide led to a reduction in safety critical errors and omitted steps when compared to baseline. It has also been found to be efficacious in supporting an individual to engage in their morning routine both in inpatient rehabilitation and home settings, involving getting out of bed and engaging in personal care (O'Neill, Best, Gillespie & O'Neill, 2013). Results showed that Guide significantly reduced the level of carer prompting required and the number of errors made in both an in-patient setting and in the participants own home.

The current study aims to investigate whether Guide can be used to support individuals with diabetes and co-morbid acquired brain injury to engage in the complex self care sequence of diabetes self-management, where they are otherwise incapable of doing so independently due to cognitive impairment.

## ***Aims and Hypotheses***

### *Aims*

To investigate whether an auditory verbal prompting system (Guide) can increase independence in diabetes self-management in individuals with diabetes and co-morbid cognitive impairment.

### *Hypothesis*

Use of Guide will result in increased independence with participants requiring less prompting from carers to complete diabetes self-management when compared to baseline.

## **Methodology**

### ***Design***

The study employed Single Case Experimental Design (SCED) methodology with a multiple baseline across subjects ABA design. In a multiple baseline across subjects design a single transition from baseline to treatment phase (AB) is instigated at a different time in each subject according to a planned staggered sequence rather than introducing the intervention to all participants at the same time. The staggered initiation of the intervention makes it implausible that behaviour change has been caused by some extraneous variable if change is seen contiguous with treatment phase onset. Barlow and colleagues (2009) identified that this type of design has high internal validity and allows for greater experimental control as behaviour changes for each subject only after the intervention has been implemented. The start date of the intervention phase for participants in the study was selected randomly.

Barnett and colleagues (2012) advocated that SCEDs are better suited than RCTs for studies in which changing patient behaviour and functional status are the primary goals and targeted sample sizes are less than 10. For these reasons the SCED was selected as the most appropriate for the current study.

An ABA format was employed with baseline, intervention and return to baseline phases. The length of the initial baseline phase for each participant was between five and ten trials. The actual length of the baseline phase for each participant was selected at random by an individual not affiliated with the study prior to the initiation of the study. The intervention phase was commenced with participant 1 following 5 baseline trials and with participant 2 following nine baseline trials. There were six intervention trials and six return to baseline trials for each participant.

### ***Ethical Approval***

Ethical approval was sought from and granted by the Scotland A Research Ethics Committee [see Appendix 2.2]. Sponsorship for the research was provided by the Brain Injury Rehabilitation Trust [see Appendix 2.3].

### ***Recruitment***

#### *Inclusion*

- Individuals with cognitive impairment and diabetes.
- Individuals identified as having difficulty independently carrying out diabetes management
- English speaking (prompts provided in English).

#### *Exclusion*

- A level of cognitive impairment that would prevent individuals from being able to follow and implement verbal prompts.

### ***Participants***

Participants were recruited from a specialist neurobehavioural assessment and post-acute rehabilitation hospital for people with complex needs as a result of a non-progressive acquired brain injury. Consent was sought both from participants and their legal guardians following provision of information on the study [See Appendix 2.4].

#### *Participant 1*

Participant 1 was a 40 year old single male. He suffered a severe acquired brain injury following a period of hypoglycaemia complicated by intravenous drug use and suspected encephalitis in his mid 30's. Brain imaging showed low attenuation from the right internal capsule to the superior right temporal lobe. He was initially admitted to an acquired brain injury unit for individuals with challenging behaviour and following a reduction in the frequency of aggression was admitted to a neurorehabilitation centre for further rehabilitation. At time of recruitment into the study, he had been resident at the unit for a period of 15 months and was considered to have severe cognitive impairment.

He had a difficult upbringing, both parents were heavy alcohol users and he was brought up in care. There was an indication of possible conduct disorder in childhood with a history of antisocial behaviour prior to injury. He attended primary school and some secondary school but left without completing any exams. He worked for a short period as a butcher's assistant. He was diagnosed with Type 1 Diabetes in childhood and prior to injury had been capable of monitoring his own blood glucose levels. However due to alcohol and intravenous drug misuse he was not engaging in this behaviour. Prior to enrolment in the study he completed some elements of monitoring independently albeit with frequent errors and a high level of supervision from nursing staff.

### *Participant 2*

Participant 2 was a 59 year old male. He attended secondary school until the age of 16 years and left without achieving any qualifications. After leaving school, he had a long history of unemployment and a history of alcohol dependence and intravenous drug misuse. In his mid 50's he experienced a basal skull fracture and small frontal lobe contusion with evidence on brain imaging of small vessel cerebrovascular disease. At this time he was admitted to a neurorehabilitation centre for a period of assessment and rehabilitation following which he was discharged home. Approximately two years subsequent to this he experienced an ischaemic cerebrovascular accident in the territory of the left middle cerebral artery followed a month later by a fall with further injury through intracerebral bleeding. This resulted in a further admission for neurorehabilitation and at time of recruitment into the study he had been resident in the unit for a period of 21 months. He experienced marked expressive and receptive dysphasia and moderate ataxia. Comprehensive neuropsychological assessment of cognition was not possible due to the level of dysphasia, however impairments were categorised as severe and it was recommended that he would need full time 24 hour care on discharge from the unit. During his first admission to the neurorehabilitation unit, his premorbid functioning was estimated to be in the average range using the Wechsler Test of Adult reading (WTAR; Holdnack, 2001). He was diagnosed with Type II Diabetes in adulthood and this was regulated through the use of insulin. His blood glucose levels were monitored at least twice per day by nursing staff and more frequently as necessary. At time of recruitment he was completely dependent on nursing staff for blood glucose monitoring.

## ***Procedure***

In order to develop the protocol of steps and prompts needed to successfully complete the task of checking blood sugar levels, the input of a Diabetes Specialist Nurse (DSN) was sought [informed consent was obtained see Appendix 2.5]. The DSN was interviewed and observed teaching a volunteer, with no prior experience, the task of diabetes self-management. The dialogue of this interaction was analysed in order to identify the steps and sub-steps involved, the prompts given, the questions used to effect accurate sequence performance and possible errors.

This information was then used to map the problem space of the task using Guide. A series of prompts (not requiring a response from the user), and checks (in the form of questions to the user requiring a 'yes' or 'no' response) relating to main steps, sub-steps and anticipated errors were entered into the system to elicit the desired sequence of behaviours in order to lead to successful task performance (See Appendices 2.6 & 2.7). The protocol was edited based on the individual needs and capabilities of the participant. The protocol used for participant 2 was broadly similar to that used for participant 1; however prompts and questions were shortened where possible in order to facilitate understanding.

Prior to enrolment in the study, participant 1 was capable of completing some steps of the sequence with assistance and prompting from nursing staff. Nursing staff performed blood sugar checks for participant 2 who did not complete or attempt to complete any part of the sequence himself. No prior training in the use of Guide was needed aside from users being instructed to answer only 'yes' or 'no'. During baseline participants were verbally prompted through the task by the first author (JM). Prompts were provided based on a schedule developed prior to the commencement of the study designed to provide the minimal amount of prompting needed to elicit task performance (see Appendix 2.8). Staff adherence to the protocol was not formally assessed. In the intervention phase Guide provided prompts to the user and asked questions of them, further verbal prompts were provided by staff only as necessary (i.e. if the participant made an error or attempted to complete steps in the wrong order). In the return to baseline phase, participants were again provided with verbal prompts by staff according to the prompting schedule in order to enable them to engage in diabetes management. All trials were conducted under the supervision of nursing staff in order to ensure participant safety. Data in all phases was recorded through video recording.



### ***Outcome Measurement***

Outcome of the intervention will be determined through the use of a measure developed specifically for the study which is similar to those used by previous studies of Guide (O'Neill et al., 2013; See Appendix 2.9). Scores are given over three areas: level of prompting needed, number of sequence steps correctly completed and number of errors made. Prompting scores require giving a prompt rating for each step of the sequence e.g. picking up the test strip tub, opening the tub, taking out one strip etc. A score of 0 points represented independent completion of the step with no prompting. One point was given for step completion after one verbal prompt, two points after two verbal prompts and three points if physical prompting was needed (i.e. pointing to relevant items). The maximum prompt score for each step was 4 points if the participant was unable to complete the step or required physical assistance. The minimum prompt score for each trial was 0 and the maximum score for each trial was 80. The maximum sequence score was twelve. One sequence point was awarded for each step completed in the correct sequence without the aid of verbal prompting. Lastly participants were given one error point for each error they made out of a list of ten possible errors e.g. putting the wrong end of the strip in the meter. All trials were scored by the main investigator. Scoring was conducted by reviewing video footage of each trial. A random selection of trials (20%) were assessed by a second rater to investigate inter rater reliability which proved to be high with agreement of 91%. Due to the nature of the intervention, it was not possible to for raters to be blinded to intervention phase.

### ***Materials***

Equipment utilised included the following:

1. Johnson & Johnson Accu-Check Aviva blood glucose monitoring device.
2. Hardware – A PC with Windows XP in order to access the Guide protocol editor. A tablet (the Nexus 10 was used but Guide is compatible with a range of tablet devices) to run the Guide app.
3. Protocol –consisting of a sequence of steps and checks which can enable users to successfully complete diabetes self-management.
4. Guide app – Guide is a specially designed app which can receive input from the user through the voice recognition capabilities of tablet devices and use this to trigger a

response to user in the form of prompts or questions based on an inputted protocol.

5. Video camera for recording of trials.

### ***Data Analysis***

There are numerous statistical techniques that have been identified as suitable for use in studies employing SCEDs. But to date no single best method has been identified for the analysis of such data (Parker & Vannest, 2009; Parker, Vannest & Davis, 2011; Ma, 2006; Solanas, Manolov & Onghena, 2010). Manolov and colleagues (2011) attempted to bring some clarity to this by comparing the effectiveness of four of these methods for estimating intervention effect. The authors concluded that data characteristics are vital for choosing an appropriate analysis procedure and therefore recommended visual inspection of data in order to inform selection of an appropriate analysis procedure. Barnett and colleagues (2012) also recommended employing visual analysis of graphed data along with statistical analysis in order to draw informed conclusions about intervention effectiveness when using SCED methodology. Following the analysis selection procedures outlined by Manolov and colleagues (2011) and visual inspection of the data for participants 1 and 2, the Nonoverlap of All Pairs (NAP; Parker & Vannest, 2009) method was selected as the most appropriate procedure.

Analysis was completed using the web based calculator for SCR research developed by Vannest and colleagues (Version 1; Vannest, Parker & Gonen, 2011). NAP represents the novel application of an established effect size known in other contexts as Area Under the Curve, Mann Whitney's U and the Dominance Statistic amongst others. The technique has been shown to be superior to other nonoverlap techniques in its precision and discrimination and in its relationship to other established effect size measures such as Pearson's  $R^2$  (Parker & Vannest, 2009). It is based on the premise that the amount of change in performance due to the introduction of an intervention can be characterised by the extent to which data in the baseline and intervention phases do not overlap. According to Parker and Vannest (2009) a NAP statistic of 0 – 0.65 represents a weak effect, 0.66 – 0.92 represents a medium effect and a strong effect is characterised by a test statistic of between 0.93 and 1.0.

## Results

### Participant 1

The NAP technique makes the assumption that there is no underlying trend in the baseline data. The Mann-Kendall test of trend along with visual inspection of the data was employed to investigate this. This test statistic was non-significant ( $p > 0.05$ ; 2-tailed) for the prompting, sequence and error data for participant 1, indicating that there was no trend present in the baseline data. The level of prompting needed for completion of blood glucose monitoring was significantly reduced for participant 1 following the introduction of Guide in the intervention phase compared with baseline performance,  $NAP = 0.97$ ,  $p < .05$ , representing a strong effect (See Figure 1). Performance in the intervention phase represented near complete independence from prompts provided by staff.

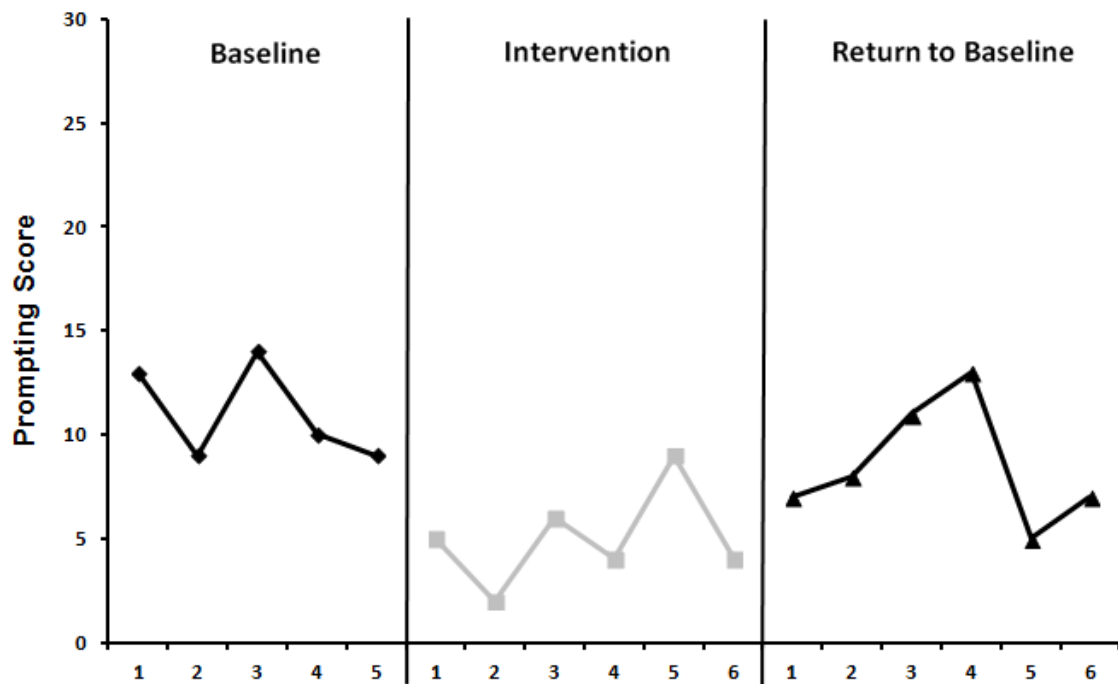


Figure 1. Prompting score at each phase for participant 1.

Sequence scores for participant 1 remained relatively stable across phases and no significant difference was found between the baseline and intervention phase,  $NAP = 0.80$ ,  $p > .05$  (see Figure 2).

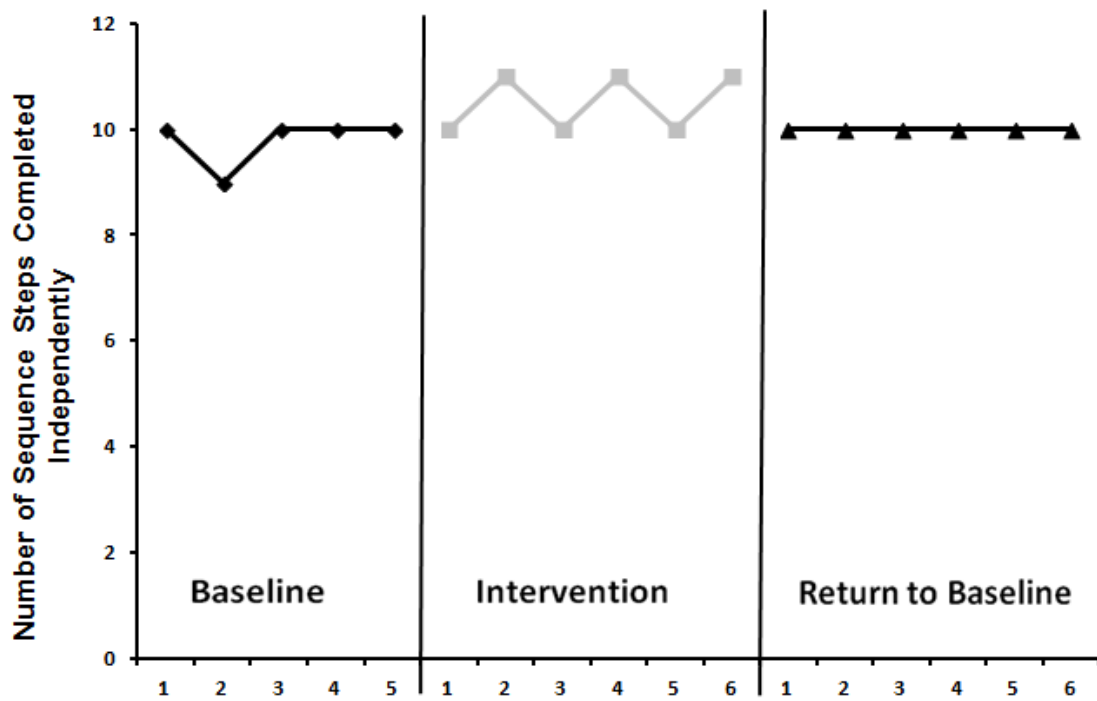


Figure 2. Sequence score at each phase for participant 1.

There was no significant difference between baseline and intervention phases in error scores for participant 1, NAP = 0.75,  $p > .05$  (see Figure 3). Common errors made in the baseline phase were using the same finger for the test rather than alternating fingers as would be good practice, pricking the finger on the tip rather than the side (pricking the finger on the tip can cause a loss of sensation in fingertips over time, therefore pricking the side of the finger is considered preferable) and licking blood from the finger rather than using a tissue. During the intervention phase participant 1 was consistently pricking the side of his finger rather than the tip, however the other errors persisted.

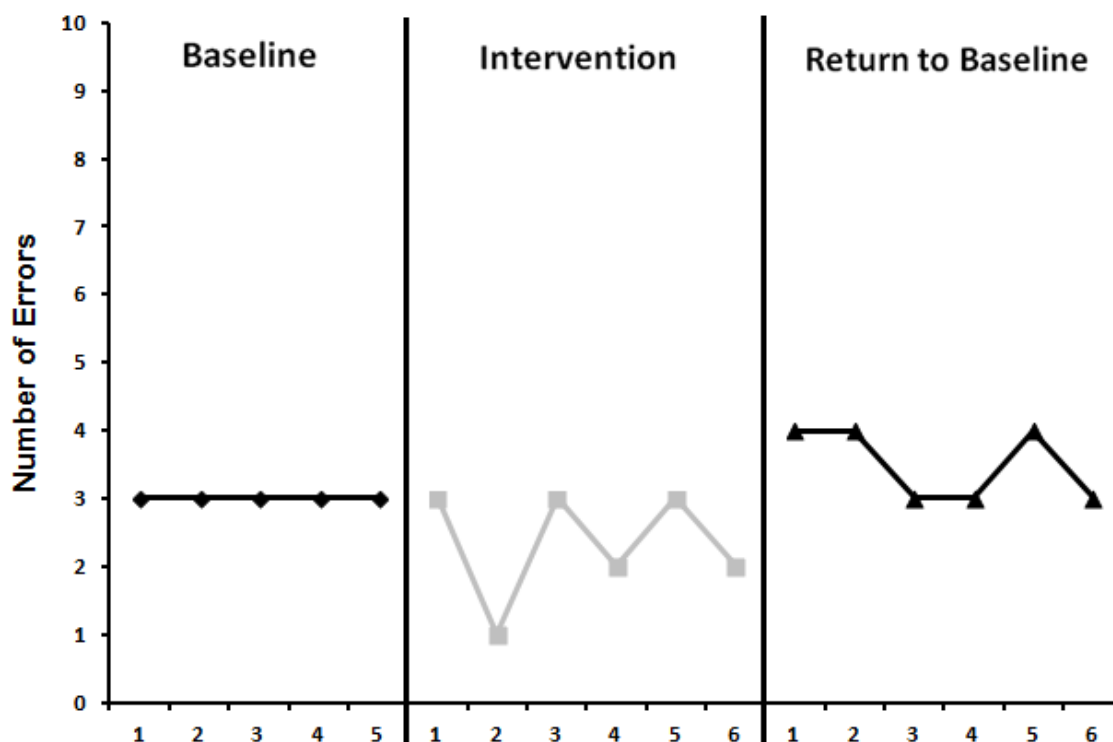


Figure 3. Number of errors made by participant 1 according to phase.

### ***Participant 2***

The Mann-Kendall test of trend was employed along with visual inspection of the data to investigate whether the assumption of no underlying trend in the baseline data was met. This test statistic was non-significant ( $p > 0.05$ ; 2-tailed) for the prompting, sequence and error data, indicating that there was no trend present in the baseline data for participant 2. The level of staff prompting needed for completion of blood glucose monitoring was significantly reduced for participant 2 following the introduction of Guide in the intervention phase compared with baseline performance,  $NAP = 0.95$ ,  $p < .01$ , representing a strong effect (see Figure 4). Prompting scores in the return to baseline phase continued to be significantly lower than the baseline phase,  $NAP = 0.90$ ,  $p < .05$ , indicating that some gains were retained post intervention.

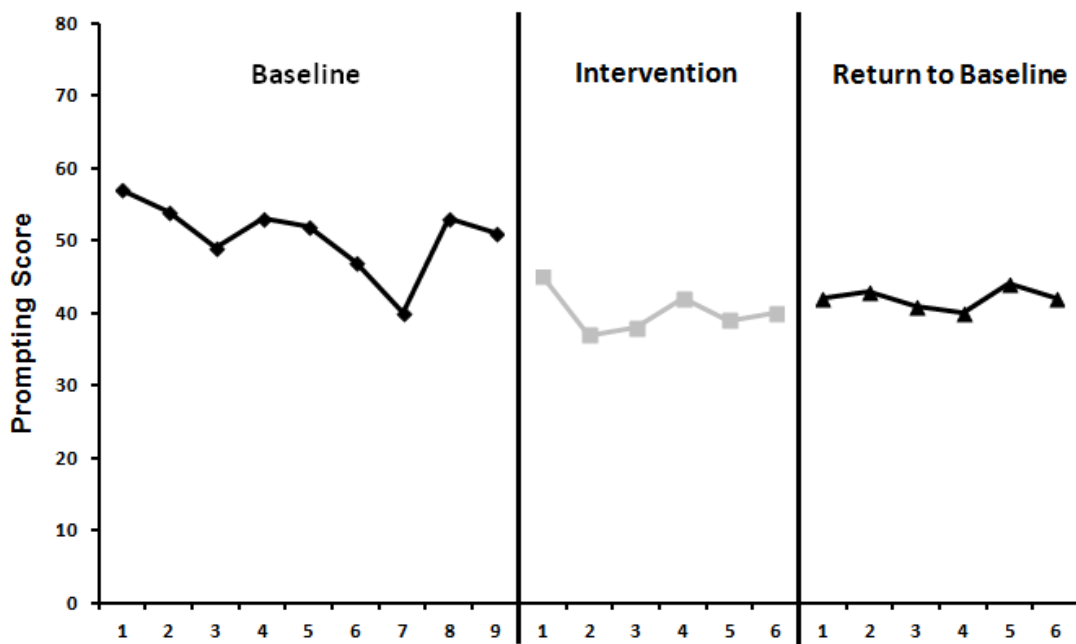


Figure 4. Prompting score at each phase for participant 2.

There was a significant improvement in sequence scores from baseline to intervention with analysis revealing a strong effect,  $NAP = 1.0$ ,  $p < .01$  (see Figure 5). Sequence scores in the return to baseline phase continued to be significantly higher than the baseline phase,  $NAP = 0.94$ ,  $p < .01$ , indicating that gains were retained post intervention.

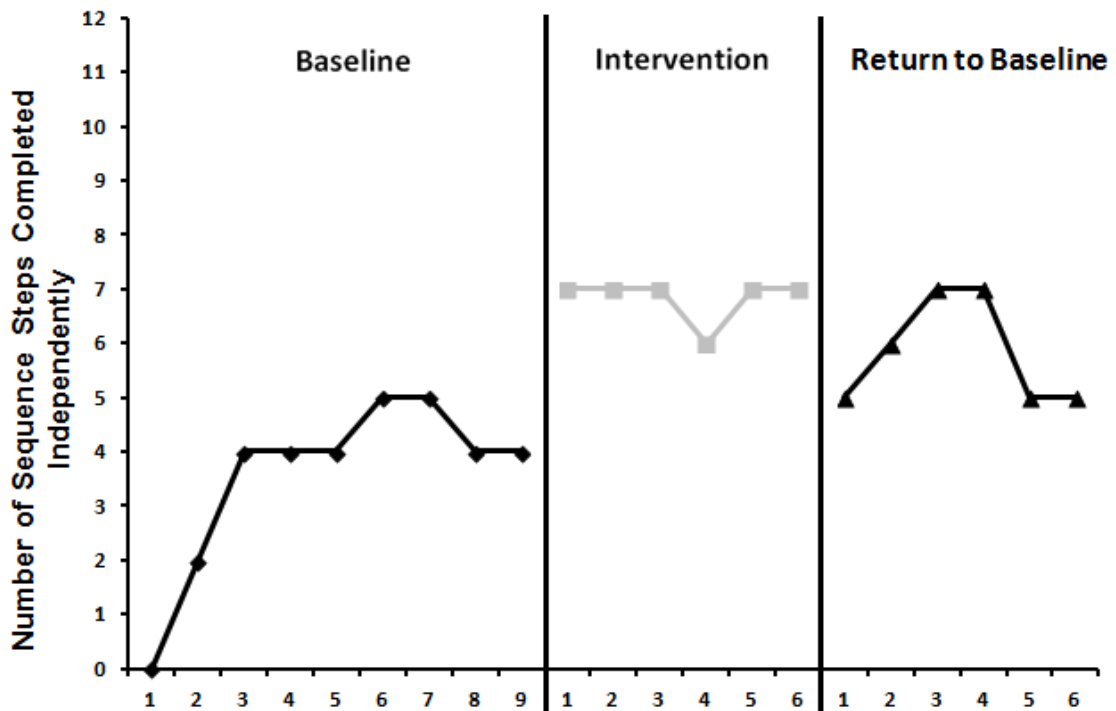


Figure 5. Sequence scores for participant 2 according to phase.

Error scores did not show any significant improvement for participant 2,  $NAP = 0.42$ ,  $p > .05$ ; however error rates were low in baseline and intervention phases due to the participant being dependent on staff for completion of a number of steps (see Figure 6).

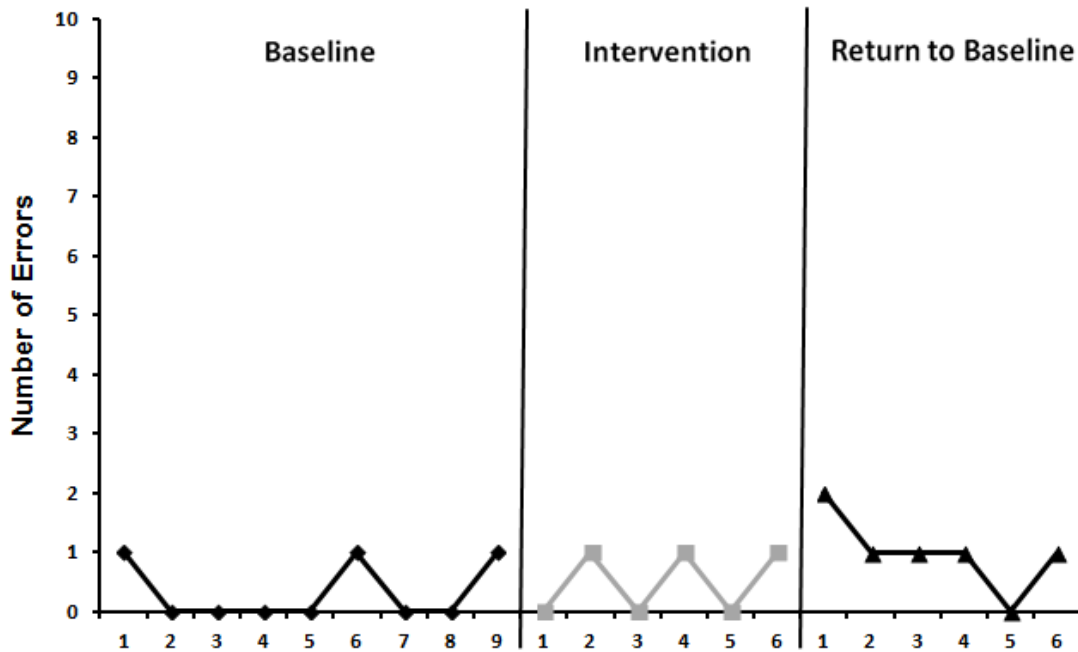


Figure 6. Number of errors made in each phase for participant 2.

## Discussion

The use of Guide prompting technology significantly reduced the amount of staff prompting needed by participants to accurately perform blood glucose monitoring. This suggests that Guide may be useful in the augmentation of carer prompting and may reduce the level of support and supervision required. Guide models the cognitive scaffolding provided by carers during complex tasks and similar to carer support it can be tailored to the individual's needs. With the aid of Guide, participant 1 could complete the main steps of the task safely in the absence of staff prompting and supervision.

Despite significant cognitive impairment, participant 2 made substantial gains, progressing from being unable to complete any of the sequence without heavy staff prompting to being able to complete roughly 50% of the steps independently in the intervention phase. Independent sequence performance levelled out at 50% of steps as the participant was unable to complete a number of steps due to manual dexterity difficulties. He struggled to hold the lancet correctly and use this to prick his finger; therefore these steps had to be carried out by staff. With appropriate equipment such as pressure

activated lancets, it is likely that with the assistance of Guide, participant 2 would have been able to achieve a higher level of performance independent of staff prompting as he demonstrated an ability to correctly sequence the steps of the task that he was physically able to complete. If the use of Guide can eliminate or reduce the need for carer support or supervision for tasks this could lead to cost savings in rehabilitation settings.

Guide has previously been shown to be effective in supporting procedural tasks and tasks with procedural and motivational elements (O'Neill et al., 2010; O'Neill et al., 2013). The current study demonstrates its effectiveness in supporting individuals to engage in complex self-care tasks. The participants in this study had a severe level of cognitive impairment, however still made significant gains with the aid of Guide technology. This suggests that individuals with a range of cognitive abilities could stand to benefit and that it could perhaps be employed more widely to support individuals with cognitive impairment due to other causes (e.g. dementia, learning difficulties). Guide is based on errorless learning principles and utilises an auditory verbal interface which is simple and intuitive to use and requires no training of the participant. For this reason Guide may be particularly useful in enabling individuals with severe cognitive impairment to engage in complex procedural tasks with a level of independence as it makes few cognitive demands of them. Guide could also be used to support individuals with cognitive impairment with other complex behavioural sequences that are generally verbally augmented by carers.

There are a significant proportion of individuals living in the community who require daily nursing input in the home to perform diabetes management as they are unable to correctly sequence the behaviour themselves. While participants in this study were both resident in an inpatient rehabilitation unit, Guide has previously been shown to be effective in the home environment in assisting individuals with cognitive impairment to engage in their morning routine (O'Neill et al., 2013). While examining the effectiveness of the Guide diabetes self-management protocol with community dwelling patients was beyond the scope of this study, it would be interesting to evaluate this in future studies.

The participant's reactions to the technology appeared to be positive. Prior to the onset of the study participant 1 in particular appeared to find the process of being prompted by staff irritating and would frequently display verbal aggression toward nursing staff if they attempted to correct his performance. Interestingly he did not show similar negative reactions to being prompted by Guide. Participant 2 also appeared to enjoy and take pride in being able to engage in some steps independently with the use of Guide. It is



possible that utilising assistive technology such as Guide may lead to decreased levels of irritation and increased self-esteem and empowerment in some users when compared with carer prompting. Individual preference for carer prompting versus more independent performance with the aid of assistive technology may depend on factors such as personality and self-esteem and these factors may merit investigation in future studies using Guide.

By the end of the study participant 1 was able to complete the essential steps of the sequence independently with the use of Guide and participant 2 was able to complete 50% of the steps independently. This served the purpose of freeing nursing staff in the rehabilitation unit up to attend to other tasks during this time and also appeared to serve the function of reducing the level of aggression directed at staff. In this way the use of Guide and other assistive technology may reduce the physical and emotional burden on carers. This may also merit investigation in future studies.

A limitation of Guide in terms of SCED methodology is that the nature of the technology means that blinded assessment is not possible which may introduce an element of bias into the assessment process. However, the videoing of all trials and the use of a predefined prompting schedule and outcome measure potentially allows for trials to be rated by a number of different raters in order to ensure reliability of the assessment process. The scope of the current study covered only the blood glucose monitoring element of diabetes self-management and did not extend to insulin administration. This could however, easily be added to the protocol of future studies. While the results of this study are promising, they are based on data from only two participants. Future evaluations of Guide employing larger sample sizes would be useful in order to confirm the findings. A larger randomised controlled trial of Guide for supporting activities such as washing laundry is currently underway and is due to report later in 2014.

## **Conclusions**

Guide may increase independence in diabetes self-management in individuals with diabetes and co-morbid cognitive impairment when compared to staff prompting. This technology may therefore represent an effective and cost efficient means of supporting cognitively impaired individuals through this complex behavioural sequence.

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### **Chapter 3: Advanced Clinical Practice 1, Reflective Critical Account**

A Reflective Account of the Development of Communication Skills during Doctoral Training  
in Clinical Psychology

Jane Moir

*Submitted in part fulfilment of the requirements for the qualification of Doctorate in  
Clinical Psychology*

## **Abstract**

**Introduction:** This account focuses on the development of a range of communication skills over the course of clinical training. Communication is recognised as a key skill for psychologists by both the Health and Care Professions Council (HCPC) in their Standards of Proficiency for Practitioner Psychologists (2012) and by the British Psychological Society (BPS) in their Generic Professional Practice Guidelines (2008), therefore this was felt to be an important area to focus on.

**Reflection:** Gibbs (1988) Reflective Cycle and Chris John's (1995) Model of Structured Reflection were employed to structure my reflections and to allow me to analyse the feelings, thoughts and emotions that particular events evoked. Areas addressed included communicating in multidisciplinary teams and the factors that lead to the successful functioning of teams and communication with clients, specifically building a strong therapeutic alliance and communicating effectively with clients with cognitive or communication impairments.

**Reflective Review:** I reflected on my experience of using the Gibbs and John's Reflective models and the elements of these that I found helpful for my reflective practice. I also discussed how my experiences of reflection have changed over the course of clinical training with this now viewed as a valuable mechanism of development for my future professional career.

## **Chapter 4: Advanced Clinical Practice 2, Reflective Critical Account**

A Reflective Account of the Development of Research Skills during Doctoral Training in Clinical Psychology and of how Clinicians can remain Actively Involved in Research Post Qualification

Jane Moir

*Submitted in part fulfilment of the requirements for the qualification of Doctorate in Clinical Psychology*

## **Abstract**

**Introduction:** This account focuses on my personal experiences of the challenges of conducting research. Research skills are recognised as a key competency for psychologists by both the Health and Care Professions Council (HCPC) in their Standards of Proficiency for Practitioner Psychologists (2012) and by the British Psychological Society (BPS) in their Generic Professional Practice Guidelines (2008), therefore I felt this to be an important area to focus on. Consideration is also given to the challenges of remaining actively involved in research following qualification and how these challenges might be overcome.

**Reflection:** Gibbs (1988) Reflective Cycle and Chris John's (1995) Model of Structured Reflection were employed to structure my reflections and to allow me to analyse the feelings, thoughts and emotions that particular events evoked. Areas addressed included the challenges of conducting research during training, the challenges of remaining involved in research post qualification and the impact that these challenges may have for the profession of psychology as a whole.

**Reflective Review:** I reflected on my experience of using the Gibbs and John's Reflective models and the elements of these that I found helpful for my reflective practice. I also discussed how the writing of this account has allowed me to appreciate the value of utilising models of reflection to reflect on areas other than clinical practice which is a skill that I will carry forward to life as a qualified clinical psychologist.

## Systematic Review Appendices

### Appendix 1.1 Instructions to authors for submission to Journal of Neurology

#### Journal of Neurology - Instructions for Authors

##### TYPES OF PAPERS

- Declaration of Conflict of Interest is mandatory for all submissions. Please refer to the section "Integrity of research and reporting" in the Instructions for Authors.
- Papers must be written in English.
- Papers must not exceed 8 printed pages (20 type-written pages of 32 lines each) plus 8 figures, taking up no more than 3 printed pages altogether. Exception to this rule can be made only with the agreement of the Joint Chief Editors.
- Letters to the Editors will be considered for publications of brief communications or case reports; they should not contain more than 800 words, 1 figure, 1 table (or 2 of either), and 15 references.

##### MANUSCRIPT SUBMISSION

###### Manuscript Submission

Submission of a manuscript implies: that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

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Authors should submit their manuscripts online. Electronic submission substantially reduces the editorial processing and reviewing times and shortens overall publication times. Please follow the hyperlink "Submit online" on the right and upload all of your manuscript files following the instructions given on the screen.

##### TITLE PAGE

###### Title Page

The title page should include:

- The name(s) of the author(s)
- A concise and informative title
- The affiliation(s) and address(es) of the author(s)
- The e-mail address, telephone and fax numbers of the corresponding author

###### Abstract

Please provide an abstract of 150 to 250 words. The abstract should not contain any undefined abbreviations or unspecified references.

###### Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

##### TEXT

###### Text Formatting

Manuscripts should be submitted in Word.

- The text of a research paper should be divided into Introduction, Materials and Methods, Results, Discussion, Acknowledgements, Conflict of Interest, and References.
- Materials and Methods must include statement of Human and Animal Rights.
- Use a normal, plain font (e.g., 10-point Times Roman) for text.
- Use italics for emphasis.
- Use the automatic page numbering function to number the pages.
- Do not use field functions.



- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Manuscripts with mathematical content can also be submitted in LaTeX.

- LaTeX macro package (zip, 182 kB)

#### Headings

Please use no more than three levels of displayed headings.

#### Abbreviations

Abbreviations should be defined at first mention and used consistently thereafter.

#### Footnotes

Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes.

#### Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section before the reference list. The names of funding organizations should be written in full.

#### SCIENTIFIC STYLE

Generic names of drugs and pesticides are preferred; if trade names are used, the generic name should be given at first mention.

#### REFERENCES

##### Citation

Reference citations in the text should be identified by numbers in square brackets. Some examples:

1. Negotiation research spans many disciplines [3].
2. This result was later contradicted by Becker and Seligman [5].
3. This effect has been widely studied [1-3, 7].

##### Reference list

The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text. Do not use footnotes or endnotes as a substitute for a reference list.

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- Journal article  
Gamelin FX, Baquet G, Berthoin S, Thevenet D, Nourry C, Nottin S, Bosquet L (2009) Effect of high intensity intermittent training on heart rate variability in prepubescent children. *Eur J Appl Physiol* 105:731-738. doi: 10.1007/s00421-008-0955-8  
Ideally, the names of all authors should be provided, but the usage of "et al" in long author lists will also be accepted:  
Smith J, Jones M Jr, Houghton L et al (1999) Future of health insurance. *N Engl J Med* 341:325-329
- Article by DOI  
Slifka MK, Whitton JL (2000) Clinical implications of dysregulated cytokine production. *J Mol Med*. doi:10.1007/s001090000086
- Book  
South J, Blass B (2001) *The future of modern genomics*. Blackwell, London
- Book chapter

Brown B, Aaron M (2001) The politics of nature. In: Smith J (ed) *The rise of modern genomics*, 3rd edn. Wiley, New York, pp 230-257

- Online document  
Cartwright J (2007) Big stars have weather too. IOP Publishing PhysicsWeb. <http://physicsweb.org/articles/news/11/6/16/1>. Accessed 28 June 2007
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Trent JW (1975) Experimental acute renal failure. Dissertation, University of California
- Always use the standard abbreviation of a journal's name according to the ISSN List of Title Word Abbreviations, see
- ISSN.org LTWA

For authors using EndNote, Springer provides an output style that supports the formatting of in-text citations and reference list.

- EndNote style (zip, 2 kB)

Authors preparing their manuscript in LaTeX can use the bibtex file `spbasic.bst` which is included in Springer's LaTeX macro package.

#### TABLES

- All tables are to be numbered using Arabic numerals.
- Tables should always be cited in text in consecutive numerical order.
- For each table, please supply a table caption (title) explaining the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table caption.
- Footnotes to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data) and included beneath the table body.

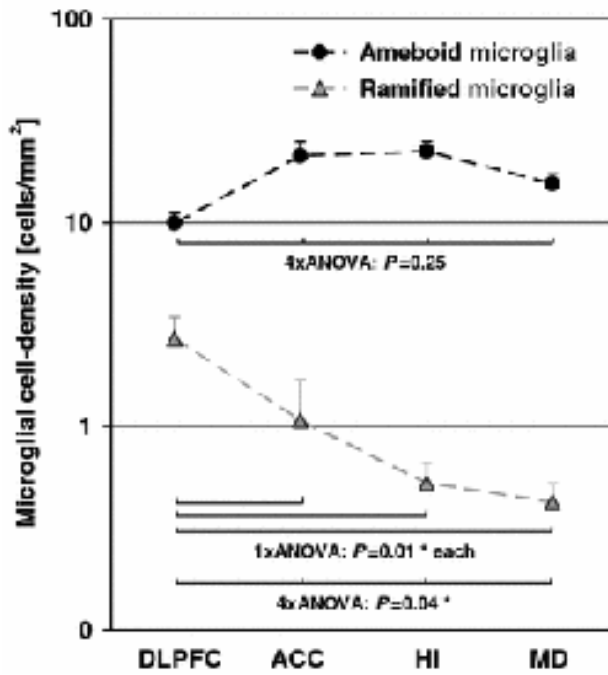
#### ARTWORK AND ILLUSTRATIONS GUIDELINES

For the best quality final product, it is highly recommended that you submit all of your artwork – photographs, line drawings, etc. – in an electronic format. Your art will then be produced to the highest standards with the greatest accuracy to detail. The published work will directly reflect the quality of the artwork provided.

##### Electronic Figure Submission

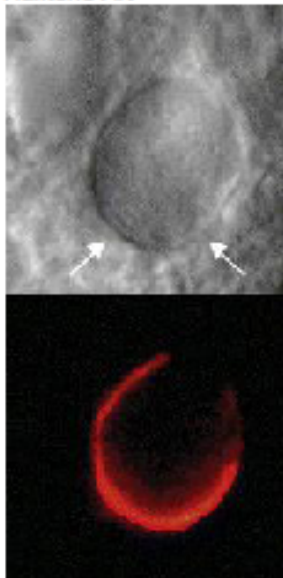
- Supply all figures electronically.
- Indicate what graphics program was used to create the artwork.
- For vector graphics, the preferred format is EPS; for halftones, please use TIFF format. MSOffice files are also acceptable.
- Vector graphics containing fonts must have the fonts embedded in the files.
- Name your figure files with "Fig" and the figure number, e.g., Fig1.eps.

##### Line Art



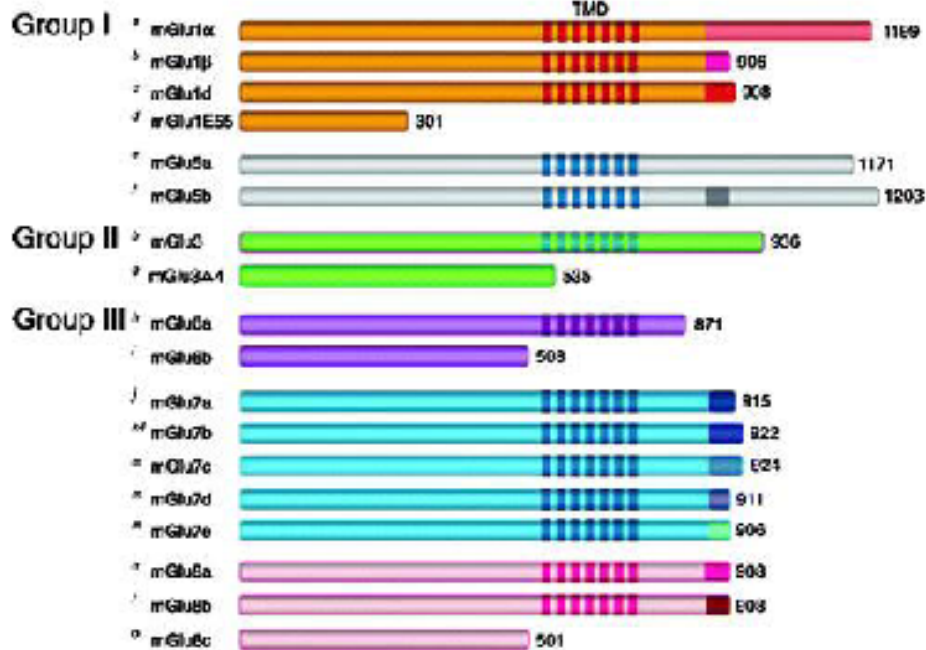
- Definition: Black and white graphic with no shading.
- Do not use faint lines and/or lettering and check that all lines and lettering within the figures are legible at final size.
- All lines should be at least 0.1 mm (0.3 pt) wide.
- Scanned line drawings and line drawings in bitmap format should have a minimum resolution of 1200 dpi.
- Vector graphics containing fonts must have the fonts embedded in the files.

#### Halftone Art



- Definition: Photographs, drawings, or paintings with fine shading, etc.
- If any magnification is used in the photographs, indicate this by using scale bars within the figures themselves.
- Halftones should have a minimum resolution of 300 dpi.

### Combination Art



- Definition: a combination of halftone and line art, e.g., halftones containing line drawing, extensive lettering, color diagrams, etc.
- Combination artwork should have a minimum resolution of 600 dpi.

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- Color art is free of charge for online publication.
- If black and white will be shown in the print version, make sure that the main information will still be visible. Many colors are not distinguishable from one another when converted to black and white. A simple way to check this is to make a xerographic copy to see if the necessary distinctions between the different colors are still apparent.
- If the figures will be printed in black and white, do not refer to color in the captions.
- Color illustrations should be submitted as RGB (8 bits per channel).

### Figure Lettering

- To add lettering, it is best to use Helvetica or Arial (sans serif fonts).
- Keep lettering consistently sized throughout your final-sized artwork, usually about 2–3 mm (8–12 pt).
- Variance of type size within an illustration should be minimal, e.g., do not use 8-pt type on an axis and 20-pt type for the axis label.
- Avoid effects such as shading, outline letters, etc.
- Do not include titles or captions within your illustrations.

### Figure Numbering

- All figures are to be numbered using Arabic numerals.
- Figures should always be cited in text in consecutive numerical order.
- Figure parts should be denoted by lowercase letters (a, b, c, etc.).
- If an appendix appears in your article and it contains one or more figures, continue the consecutive numbering of the main text. Do not number the appendix figures, "A1, A2, A3, etc." Figures in online appendices (Electronic Supplementary Material) should, however, be numbered separately.

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- Figure captions begin with the term Fig. in bold type, followed by the figure number, also in bold type.
- No punctuation is to be included after the number, nor is any punctuation to be placed at the end of the caption.
- Identify all elements found in the figure in the figure caption; and use boxes, circles, etc., as coordinate points in graphs.
- Identify previously published material by giving the original source in the form of a reference citation at the end of the figure caption.

#### **Figure Placement and Size**

- When preparing your figures, size figures to fit in the column width.
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- For books and book-sized journals, the figures should be 80 mm or 122 mm wide and not higher than 198 mm.

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- In order to give people of all abilities and disabilities access to the content of your figures, please make sure that
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- Patterns are used instead of or in addition to colors for conveying information (colorblind users would then be able to distinguish the visual elements)
- Any figure lettering has a contrast ratio of at least 4.5:1

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Springer accepts electronic multimedia files (animations, movies, audio, etc.) and other supplementary files to be published online along with an article or a book chapter. This feature can add dimension to the author's article, as certain information cannot be printed or is more convenient in electronic form.

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- Supply all supplementary material in standard file formats.
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- To accommodate user downloads, please keep in mind that larger-sized files may require very long download times and that some users may experience other problems during downloading.

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- Always use MPEG-1 (.mpg) format.

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- If the readers should be encouraged to make their own calculations, spreadsheets should be submitted as .xls files (MS Excel).

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- Specialized format such as .pdb (chemical), .vrl (VRML), .nb (Mathematica notebook), and .tex can also be supplied.

#### **Collecting Multiple Files**

- It is possible to collect multiple files in a .zip or .gz file.

#### **Numbering**

- If supplying any supplementary material, the text must make specific mention of the material as a citation, similar to that of figures and tables.
- Refer to the supplementary files as "Online Resource", e.g., "... as shown in the animation (Online Resource 3)", "... additional data are given in Online Resource 4".
- Name the files consecutively, e.g. "ESM\_3.mpg", "ESM\_4.pdf".

#### **Captions**

- For each supplementary material, please supply a concise caption describing the content of the file.

#### **Processing of supplementary files**

- Electronic supplementary material will be published as received from the author without any conversion, editing, or reformatting.

#### **Accessibility**

In order to give people of all abilities and disabilities access to the content of your supplementary files, please make sure that

- The manuscript contains a descriptive caption for each supplementary material
- Video files do not contain anything that flashes more than three times per second (so that users prone to seizures caused by such effects are not put at risk)

### **INTEGRITY OF RESEARCH AND REPORTING**

#### **Ethical standards**

Manuscripts submitted for publication must contain a statement to the effect that all human and animal studies have been approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

It should also be stated clearly in the text that all persons gave their informed consent prior to their inclusion in the study. Details that might disclose the identity of the subjects under study should be omitted.

These statements should be added in a separate section before the reference list. If these statements are not applicable, authors should state: The manuscript does not contain clinical studies or patient data.

The editors reserve the right to reject manuscripts that do not comply with the above-mentioned requirements. The author will be held responsible for false statements or failure to fulfill the above-mentioned requirements

#### **Conflict of interest**

Authors must indicate whether or not they have a financial relationship with the organization that sponsored the research. This note should be added in a separate section before the reference list. If no conflict exists, authors should state: The authors declare that they have no conflict of interest.

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##### **Online First**

The article will be published online after receipt of the corrected proofs. This is the official first publication citable with the DOI. After release of the printed version, the paper can also be cited by issue and page numbers.

Appendix 1.2 Clinical trials Assessment measure (Tarrier & Wykes, 2004)

**Reviewer Name:**

**Paper Reviewed:**

**Date:**

**Clinical Trials Assessment Measure (Tarrier & Wykes, 2004)**

		Score
<b>Sample</b>		
1	Is the sample a convenience sample (score 2) or a geographic cohort (score 5) or highly selective sample (score 0) ( <i>Convenience sample: e.g. clinic attendees, referred patients. Geographic cohort : all patients eligible in a particular area</i> )	
2	Is the sample size greater than 27 participants per group (score 5) or based on adequate and described power calculations (score 5) If no to both questions score 0.	
<i>Subtotal</i>		<i>/10</i>
<b>Allocation</b>		
3	Is there true random allocation or minimisation allocation to treatment groups (if yes score 10)	
4	Is the process of randomisation described (score 3)	
5	Is the process of randomisation carried out independently from the trial research team (score 3)	
<i>Subtotal</i>		<i>/16</i>
<b>Assessment (for the main outcome)</b>		
6	Are the assessments carried out by independent assessors and not therapists (score 10)	
7	Are standardised assessments used to measure symptoms in a standardised way (score 6), idiosyncratic assessments of symptoms (score 3)	



8	Are assessments carried out blind (masked) to treatment group allocation (score 10)	
9	Are the methods of rater blinding adequately described (score 3)	
10	Is rater blinding verified (score 3)	
<i>Subtotal</i>		<i>/32</i>
<b>Control Groups</b>		
11	TAU is a control group (score 6) and/or a control group that controls for non-specific effects or other established or credible treatment (score 10)	
<i>Subtotal</i>		<i>/16</i>
<b>Analysis</b>		
12	The analysis is appropriate to the design and type of outcome measure (score 5)	
13	The analysis includes all those participants as randomised (sometimes referred to as an intention to treat analysis) (score 6) and an adequate investigation and handling of drop outs from assessment if the attrition rate exceeds 15% (score 4)	
<i>Subtotal</i>		<i>/15</i>
<b>Active Treatment</b>		
14	Was the treatment adequately described (score 3) and was a treatment protocol or manual used (score 3)	
15	Was adherence to the treatment protocol or treatment quality assessed (score 5)	
<i>Subtotal</i>		<i>/11</i>
<b>Total Score</b>		<b><i>/100</i></b>

## Major Research Project Appendices

### Appendix 2.1 Instructions to authors for submission to Neuropsychological Rehabilitation

#### SCHOLARONE MANUSCRIPTS\*

This journal uses ScholarOne Manuscripts (previously Manuscript Central) to peer review manuscript submissions. Please read the [guide for ScholarOne authors](#) before making a submission. Complete guidelines for preparing and submitting your manuscript to this journal are provided below.

Use these instructions if you are preparing a manuscript to submit to *Neuropsychological Rehabilitation*. To explore our journals portfolio, visit <http://www.tandfonline.com/>, and for more author resources, visit our [Author Services](#) website.

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## Manuscript preparation

### 1. Journal-specific guidelines

- This journal accepts original (regular) articles, scholarly reviews, and book reviews.
- The style and format of the typescripts should conform to the specifications given in the Publication Manual of the American Psychological Association (6th ed.).
- There is no word limit for manuscripts submitted to this journal. Authors should include a word count with their manuscript.

### 2. General guidelines

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- Manuscripts are accepted in English. Oxford English Dictionary spelling and punctuation are preferred. Please use double quotation marks, except where “a quotation is ‘within’ a quotation”. Long quotations of words or more should be indented without quotation marks.
- Manuscripts should be compiled in the following order: title page; abstract; keywords; main text; acknowledgements; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figure caption(s) (as a list).
- [Abstracts](#) of 150-200 words are required for all manuscripts submitted.
- Each manuscript should have up to 5 [keywords](#) .
- Search engine optimization (SEO) is a means of making your article more visible to anyone who might be looking for it. Please consult our guidance [here](#) .
- Section headings should be concise.
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- Authors must not embed [equations](#) or image files within their manuscript

## 3. Figures

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- Please provide the highest quality figure format possible. Please be sure that all imported scanned material is scanned at the appropriate resolution: 1200 dpi for line art, 600 dpi for grayscale and 300 dpi for colour.
- Figures must be saved separate to text. Please do not embed figures in the manuscript file.
- Files should be saved as one of the following formats: TIFF (tagged image file format), PostScript or EPS (encapsulated PostScript), and should contain all the necessary font information and the source file of the application (e.g. CorelDraw/Mac, CorelDraw/PC).
- All figures must be numbered in the order in which they appear in the manuscript (e.g. Figure 1, Figure 2). In multi-part figures, each part should be labelled (e.g. Figure 1(a), Figure 1(b)).
- Figure captions must be saved separately, as part of the file containing the complete text of the manuscript, and numbered correspondingly.
- The filename for a graphic should be descriptive of the graphic, e.g. Figure1, Figure2a.

## 4. Publication charges

- [Information about supplemental online material](#)

## Manuscript submission

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All submissions should be made online at the *Neuropsychological Rehabilitation* [Scholar One Manuscripts](#) website. New users should first create an account. Once logged on to the site, submissions should be made via the Author Centre. Online user guides and access to a helpdesk are available on this website.

Manuscripts may be submitted in any standard editable format, including Word and EndNote. These files will be automatically converted into a PDF file for the review process. LaTeX files should be converted to PDF prior to submission because ScholarOne Manuscripts is not able to convert LaTeX files into PDFs directly. All LaTeX source files should be uploaded alongside the PDF.

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Direct Line: 0131 465 5680  
Email: [walter.hunter@nhslothian.scot.nhs.uk](mailto:walter.hunter@nhslothian.scot.nhs.uk)

Dear Miss Moir

**Study title: Supporting Diabetes Self-management in Persons with Cognitive  
Impairment after Acquired Brain Injury**  
**REC reference: 14/SS/0001**  
**IRAS project ID: 128217**

Thank you for your letter of 28 March 2014, 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.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Mr Walter Hunter, [walter.hunter@nhslothian.scot.nhs.uk](mailto:walter.hunter@nhslothian.scot.nhs.uk).

**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.

**Chairman Dr Ian Zealley  
Vice-Chairman Dr Colin Selby**

## Ethical review of research sites

### NHS 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).

### Non-NHS sites

I am pleased to confirm that the favourable opinion applies to the following research site(s), subject to site management permission being obtained prior to the start of the study at the site (see under 'Conditions of the favourable opinion below').

Research Site	Principal Investigator / Local Collaborator
Brain Injury Rehabilitation Trust, Graham Anderson House	Dr Brian O'Neill

### Conditions of the favourable opinion

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

1. The consent forms should seek specific consent for the video element of the study
2. The professional (nurses) consent form should refer to the latest version of the information sheet i.e. version 2 dated 14 March 2014.
3. Given the modification to the welfare guardian/nearest relative consent form an asterisk should be placed where nearest relative/guardian appears and an indication that this means 'delete as appropriate'.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

**Management permission or approval must be obtained from each host organisation prior**



to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study 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>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

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

#### Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett ([catherineblewett@nhs.net](mailto:catherineblewett@nhs.net)), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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
REC application: IRAS Form 3.5		22 November 2013
Protocol	5	08 November 2013
Investigator CV: Miss Moir		16 September 2013
Other: Investigator CV: Professor Evans		30 September 2013
Participant Information Sheet: Participant (BIRT)	3	14 March 2014
Participant Consent Form: Participant (BIRT)	3	14 March 2014
Participant Information Sheet: Participant (SGH)	2	14 March 2014
Participant Consent Form: Participant (SGH)	2	14 March 2014
Participant Information Sheet: Welfare Guardian/Nearest Relative	3	14 March 2014
Participant Consent Form: Welfare Guardian/Nearest Relative	3	14 March 2014
Participant Information Sheet: Professional: Nurse	2	14 March 2014
Participant Consent Form: Professional: Nurse	2	14 March 2014
Evidence of insurance or indemnity		20 November 2013
Evidence of insurance or indemnity		16 August 2013
Letter from Sponsor		20 November 2013
Letter from Sponsor: BIRT		05 February 2014
Response to Request for Further Information		05 February 2014
Response to Request for Further Information		28 March 2014

## Statement of compliance

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

## After ethical review

### Reporting requirements

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
- Notification of serious breaches of the protocol
- 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.

#### Feedback

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.

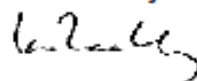
Further information is available at National Research Ethics Service website > After Review

**REC reference number: 14/SS/0001-Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely



**Dr Ian Zealley**  
**Committee Chairman**

cc: Dr Brian O'Neill, Brain Injury Rehabilitation Trust  
Mr Raymond Hamill, NHS Lanarkshire

Appendix 2.2 (ii) Letter confirming compliance with conditions of ethical approval.

**Scotland A Research Ethics  
Committee**

Research Ethics Service  
2<sup>nd</sup> Floor Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
EH1 3EG  
Telephone: 0131 465 5680  
Fax: 0131 465 5789  
www.nres.nhs.uk



Miss Jane Moir  
Trainee Clinical Psychologist  
NHS Lanarkshire  
c/o Institute of Mental Health and  
Wellbeing  
University of Glasgow  
Gartnavel Royal Hospital  
Glasgow  
G12 0XH

Date: 3 April 2014  
Your Ref.:  
Our Ref.: 14/SS/0001  
Enquiries to: Walter Hunter  
Extension: 35680  
Direct Line: 0131 465 5680  
Email: walter.hunter@nhslothian.scot.nhs.uk

Dear Miss Moir

**Study title: Supporting Diabetes Self-management in Persons with Cognitive Impairment after Acquired Brain Injury**

**REC reference: 14/SS/0001**

**IRAS project ID: 128217**

Thank you for your le-mail dated 2 April 2014. I can confirm the Scotland A REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 1 April 2014

**Documents received**

The documents received were as follows:

Document	Version	Date
Participant Consent Form: Participant: BIRT	4	01 April 2014
Participant Consent Form: Participant: SGH	3	01 April 2014
Participant Consent Form: Welfare Guardian/Nearest Relative	4	01 April 2014
Participant Consent Form: Professional: Nurse	3	01 April 2014

**Approved documents**

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
REC application: IRAS Form 3.5		22 November 2013

**Chairman Dr Ian Zealley  
Vice-Chairman Dr Colin Selby**

## Appendix 2.3 Sponsorship Letter



Sue Copstick  
Clinical Director  
The Disabilities Trust  
Kerwin Court  
Horsham  
Surrey

Walter Hunter  
Scotland A Research Ethics Committee  
NHS Lothian  
Waverley Gate  
2 - 4 Waterloo Place  
Edinburgh  
EH1 3EG

17.04.2014


To Whom It May Concern:

**Re: Project Title: Supporting Diabetes Self-management in Persons with Cognitive Impairment after Acquired Brain Injury  
Scotland A REC Reference:14/SS/001**

I have reviewed the protocol, dated 15.4.2013, for the above study. Diabetes is a critical medical condition which presents management challenges for those with acquired brain injury and this proposal is a positive approach, with the possibility of wider applications.

The project seems to be feasible within the resources of the researcher and those of BIRT as host organisation. I would thus like to endorse the project and offer the support of BIRT clinicians and sites in the running of this study.

Yours faithfully,

  
Sue Copstick  
Clinical Director

[www.birt.co.uk](http://www.birt.co.uk)

The Disabilities Trust is a company limited by guarantee, incorporated in England and Wales under 209599, registered office as shown. It is registered as a charity in England and Wales under 800797 (BIRT 800797/1) and in Scotland under SC114977 (BIRT 5004572). Registered office: 32 Market Road, Burgess Hill, West Sussex BN15 4NR. The Brain Injury Rehabilitation Trust (BIRT) is a division of The Disabilities Trust and the means by which The Disabilities Trust provides its brain injury services.





## Information Sheet - Participant

### Independent Diabetes Self-Management

You are invited to take part in a research study. Before you decide it is important to understand why we are doing the research and what it will involve. Please take time to read this information and discuss it with someone. If you would like more information, please ask. Take time to decide whether you'd like to take part. Thank you for reading.

### What is the purpose of the study?

The study aims to test a new approach to teaching diabetes self-management.

### Why have I been chosen?

You have been chosen to participate as you have been having problems checking your blood glucose independently. We believe the study may help you to be able to do this.

### Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you remain free to withdraw from the study at any time and without giving a reason. Not taking part, will not affect the care you receive.

### What will happen to me if I take part?

A member of the research team will observe you engaging in diabetes self-management when assisted by a member of nursing staff on 6 occasions. Video recording will be used for some aspects of the data recording. To test the intervention, you will be asked to listen to some prompts that talk you through the steps of the task for 6 trials. After the intervention you will again be observed completing the activity on 6 occasions.

### What is the procedure that is being tested?

A cognitive aid known as Guide is being tested. It consists of special speakers and a microphone. These are to enable you to communicate with a computer that stores an 'action plan' of the steps involved in checking your blood sugars. The computer will then tell you how to do the task. You will be accompanied by a research assistant during these procedures.

### What are the alternatives for treatment?

If you chose not to take part, normal rehabilitation will continue.

### What are the possible disadvantages and risks of taking part?

We foresee no risks or disadvantages associated with this study.

### What are the possible benefits of taking part?

Intended benefits include being better able to remember how to check your blood glucose so that you will be more able to carry this out independently. Previous research has shown that GUIDE was able to help people with brain injuries to complete their morning routine and to put on their prosthetic limbs.

**What happens when the research stops?**

The treatment will not be available after the research finishes but we hope you may retain some benefits.

**Will my taking part in this study be kept confidential?**

All information collected about you during the project will be kept strictly confidential. You will not be identifiable from information gathered.

**What will happen to the results and data of the research study?**

The results of the study are likely to be published in a specialist journal within two years of the study coming to a close. You will not be identified in any report. If the treatment proves to be effective, larger studies may be completed in the future. The data from the study will be stored in a secure manner for up to 3 years and may be used in future studies if you agree to this.

**Complaints**

If you have any complaints about the study please speak to Sandra Wylie, Service Manager at the Brain Injury Rehabilitation Trust, Graham Anderson House, 1161 Springburn Road, Glasgow, G21 1UU. Tel: 0141 4046060.

**Who is organising and funding the research?**

The research is being organised and funded by the University of Glasgow and the Brain Injury Rehabilitation Trust.

**Who has reviewed the study?**

The study has been reviewed by independent researchers at the University of Glasgow. The study was approved by the Research Ethics Committee for Scotland, A.

**Contacts for Further Information**

For further information please contact:

Jane Moir  
Trainee Clinical Psychologist, 01236 707724  
or  
Dr Brian O'Neill  
Consultant in Neuropsychology and Rehabilitation, 0141 4046060

Should you agree to take part, we would like to take this opportunity to thank you for participating.



## Consent Form - Participant

### Independent Diabetes Self-Management

Patient name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

	Please Initial	
	Yes	No
Have you read the Participant Information Sheet (version number 3, 14.03.2014)?	_____	_____
Have you had the opportunity to ask questions and to discuss the study?	_____	_____
Have you received satisfactory answers to all of your questions?	_____	_____
Have you received enough information about the study?	_____	_____

Who have you spoken to?

Dr / Mr / Mrs / Ms \_\_\_\_\_

Do you understand that you are free to withdraw from the study:

	Please Initial	
	Yes	No
At any time?	_____	_____
Without having to give a reason?	_____	_____
Without affecting your future medical care?	_____	_____
Do you agree to take part in this study?	_____	_____

	Please Initial	
	Yes	No
Do you agree to anonymised data being used in future studies?	_____	_____
Do you agree to be videoed as part of the study (your face will not be filmed)?	_____	_____

Signed \_\_\_\_\_ Date \_\_\_\_\_

Name in block letters \_\_\_\_\_

Signature of witness \_\_\_\_\_ Date \_\_\_\_\_

Name in block letters \_\_\_\_\_





## **Information Sheet for Guardian**

### **Independent Diabetes Self-Management**

Your relative is invited to take part in a research study. Your relative does not have the capacity to provide informed consent to take part in the study. Therefore you are being asked to decide whether participating is something they would have wanted. To make this decision, it is important you understand why we are doing the research and what it will involve. Please take time to read this information and decide. If you would like more information, please see the contacts below. Thank you for reading.

#### **What is the purpose of the study?**

The study aims to test a new approach to teaching diabetes self-management.

#### **Why has my relative been chosen?**

Your relative has been chosen to participate as they are experiencing difficulty in managing their diabetes independently. We believe the study may help them and others to achieve this.

#### **Do they have to take part?**

It is up to you to decide whether or not they take part based on what you think your relative would have wanted to do. If you do decide they should take part you remain free to withdraw them from the study at any time and without giving a reason. Not taking part, will not affect the care they receive.

#### **What will happen to my relative if I allow them to take part?**

A member of the research team will observe them engaging in diabetes self-management when assisted by a member of nursing staff on 6 occasions. Video recording will be used for some aspects of the data recording. To test the intervention, they will be asked to listen to some prompts that talk you through the steps of the task on 6 occasions. After the intervention they will again be observed completing the activity on 6 occasions.

#### **What is the procedure that is being tested?**

A cognitive aid known as GUIDE is being tested. It consists of special speakers and a microphone. These are to allow people to communicate with a computer that stores an 'action plan' of the steps involved. The computer will then tell your relative how to do the task. Your relative will be accompanied by a research assistant during these procedures.

#### **What are the alternatives for treatment?**

If your relative does not take part, normal support will continue.

#### **What are the possible disadvantages and risks of taking part?**

We foresee no risks or disadvantages associated with this study.

**What are the possible benefits of taking part?**

Intended benefits include being better able to remember how to check their blood glucose so that they will be more likely to carry this out independently. Previous research has shown that GUIDE was able to help people with brain injuries to complete their morning routine and to put on their prosthetic limbs.

**What happens when the research stops?**

The treatment will not be available after the research finishes but it is hoped that there may be some lasting benefit to participants.

**Will my relative's taking part in this study be kept confidential?**

All information collected about your relative during the project will be kept strictly confidential. They will not be identifiable from information gathered.

**What will happen to the results and data of the research study?**

The results are likely to be published in a specialist journal within two years of the study coming to a close. Your relative will not be identified in any report. If the treatment proves to be effective, larger studies may be completed in the future. The data from the study will be stored in a secure manner for up to 3 years and may be used in future studies if you agree to this.

**Complaints**

If you have any complaints about the study please speak to Sandra Wylie, Service Manager at the Brain Injury Rehabilitation Trust, Graham Anderson House, 1161 Springburn Road, Glasgow, G21 1UU. Tel: 0141 4046060.

**Who is organising and funding the research?**

The research is being organised and funded by the University of Glasgow and the Brain Injury Rehabilitation Trust.

**Who has reviewed the study?**

The study has been reviewed by independent researchers at the University of Glasgow. The study was approved by the Research Ethics Committee for Scotland, A.

**Contacts for Further Information**

For further information please contact:

Jane Moir  
Trainee Clinical Psychologist, 01236 707724  
or  
Dr Brian O'Neill  
Consultant in Neuropsychology and Rehabilitation, 0141 4046060

Should you agree on your relative's behalf that they should take part, we would like to take this opportunity to thank you for allowing them to participate.



## Consent Form (Guardian Version)

### Independent Diabetes Self-Management

Patient name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

	Please Initial	
	Yes	No
Have you read the Guardian Information Sheet (Version 3, 14.03.2014)?	_____	_____
Have you had the opportunity to ask questions and to discuss the study?	_____	_____
Have you received satisfactory answers to all of your questions?	_____	_____
Have you received enough information about the study?	_____	_____
Who have you spoken to?      Dr / Mr / Mrs / Ms _____		

Do you understand that the person you are acting for is free to withdraw from the study:

	Please Initial	
	Yes	No
At any time?	_____	_____
Without having to give a reason?	_____	_____
Without affecting their future medical care?	_____	_____
Do you agree for the person you are acting for to take part in this study?	_____	_____
	Yes	No
Do you agree to anonymised data being used in future studies?	_____	_____
Do you agree for the person you are acting for to be videoed as part of the study (their face will not be filmed)?	_____	_____

I confirm that I am the nearest relative/welfare guardian\* for \_\_\_\_\_  
 and that no other welfare guardian/attorney exists.  
*\* delete as appropriate*

Signed	_____	Relationship to patient	_____
Name in block capitals	_____	Date	_____
Signature of witness	_____		
Name in block capitals	_____	Date	_____



## **Information Sheet – Professional**

### **Teaching Diabetes Self-Management**

You are invited to take part in a research study. Before you decide it is important to understand why we are doing the research and what it will involve. Please take time to read this information and discuss it with someone. If you would like more information, please ask. Take time to decide whether you'd like to take part. Thank you for reading.

#### **What is the purpose of the study?**

The aim of the study is to test a new approach to teaching diabetes self-management to people who have had a brain injury and have trouble learning how to do this. We are interested in benefiting from your expertise by observing how you teach and explain to people how to check their blood glucose levels.

#### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you remain free to withdraw from the study at any time and without giving a reason.

#### **What will happen to me if I take part?**

A member of the research team will video you teaching individuals how to check their blood glucose levels. In particular we are interested in how you explain the process to people, what questions they usually ask and what prompts you give to guide them through the process. You will not be able to be identified from the recording as your face will not be filmed.

#### **What are the possible disadvantages and risks of taking part?**

We foresee no risks or disadvantages associated with this study.

#### **What are the possible benefits of taking part?**

Your participation may help us to be able to teach people who have had a brain injury how to check their blood sugar levels independently. Previous research has shown that GUIDE was able to help people with brain injuries to complete their morning routine and to put on their prosthetic limbs.

#### **Will my taking part in this study be kept confidential?**

All information collected about you will be kept strictly confidential. You will not be identifiable from information gathered.



### **What will happen to the results and data of the research study?**

The results of the study are likely to be published in a specialist journal within two years of the study coming to a close. You will not be identified in any report. Your data will be stored in a secure manner for the duration of the study and will be destroyed following its completion.

### **Complaints**

If you have any complaints about the study or the conduct of the researcher, please speak to Prof. Tom McMillan, Research Director, Doctorate in Clinical psychology, University of Glasgow (telephone 0141 2110694).

### **Who is organising and funding the research?**

The research is being organised and funded by the University of Glasgow and the Brain Injury Rehabilitation Trust.

### **Who has reviewed the study?**

The study has been reviewed by independent researchers at the University of Glasgow. The study was approved by the Research Ethics Committee for Scotland, A.

### **Contacts for Further Information**

For further information please contact:

Jane Moir  
Trainee Clinical Psychologist, 01236 707724  
or  
Dr Brian O'Neill  
Consultant in Neuropsychology and Rehabilitation, 0141 4046060

Should you agree to take part, we would like to take this opportunity to thank you for participating.



## Consent Form – Diabetes Specialist Nurse SGH

### Teaching Diabetes Self-Management

Name: \_\_\_\_\_

To be completed by the Diabetes Specialist Nurse

	Please Initial	
	Yes	No
Have you read the Professionals Information Sheet SGH (version number 2, 14.03.2014)?	_____	_____
Have you had the opportunity to ask questions and to discuss the study?	_____	_____
Have you received satisfactory answers to all of your questions?	_____	_____
Have you received enough information about the study?	_____	_____

Who have you spoken to?

Dr / Mr / Mrs / Ms \_\_\_\_\_

Do you understand that you are free to withdraw from the study:

	Please Initial	
	Yes	No
At any time?	_____	_____
Without having to give a reason?	_____	_____
Do you agree to take part in this study?	_____	_____

	Please Initial	
	Yes	No
Do you agree to anonymised data being used in future studies?	_____	_____
Do you agree to be videoed as part of the study (your face will not be filmed)?	_____	_____

Signed \_\_\_\_\_ Date \_\_\_\_\_

Name in block letters \_\_\_\_\_

Signature of witness \_\_\_\_\_ Date \_\_\_\_\_

Name in block letters \_\_\_\_\_

\* Image removed due to copyright

\* Image removed due to copyright



### **Prompt Schedule – Blood Glucose Monitoring**

The following is a list of prompts that can be provided to participants at each phase if they cannot complete a step unaided:

1. Open the test strip tub
2. Take out one strip
3. Close the tub
4. Put the strip in the meter (gold end first)
5. Pick up the lancet
6. Take off the lid
7. Select a finger to use (try to use a different finger to the one you used last time)
8. Hold the lancet to the side of your finger
9. Click the lancet to prick your finger
10. Put the used lancet in the sharps box
11. Squeeze your finger to get some blood
12. Pick up the meter
13. Hold the end of the test strip to the blood on your finger until it beeps
14. Remove the strip from the meter
15. Place the used strip in the sharps box
16. Tidy up – put all items back in the bag

Allow the participant 5 seconds to start the first step of the task before providing a prompt. Increasing prompts may be provided in the order specified below if the participant fails to start the step or starts an incorrect step. Wait 5 seconds between providing each level of prompt to allow the participant to respond:

- 1<sup>st</sup> verbal prompt
- 2<sup>nd</sup> verbal prompt
- Point to the correct item/task whilst repeating verbal prompt
- Provide physical assistance e.g. hand them the correct item/assist them with completing the step.

## Diabetes Recording Sheet

Service User ID:

Date	1	2	3	4	5	6
Picks up test strip tub						
Open test strip tub						
Take out one strip						
Closes tub						
Picks up meter						
Puts strip in meter						
Picks up lance						
Pulls off white cap						
Pricks finger						
Puts lance in sharps box						
Squeezes finger or holds hand down						
Picks up meter						
Places strip on top of blood						
Uses tissue to stop blood						
Checks reading						
States how much insulin needed						
Takes strip out						
Puts used strip in sharps box						
Puts meter away						
Puts strips away						

0 = Completes step independently

1 = Completes step after 1 verbal prompt

2 = Completes step after 2 verbal prompts

3 = Requires physical prompt e.g. pointing to items

4 = Requires physical intervention / assistance to start, continue or complete step e.g. guides hand or requires step to be completed for them

R = Refuses to complete step.

N/E = No evidence

## Sequence Completion

Open tub						
Takes out strip						
Close tub						
Picks up strip/meter						
Puts strip in meter						
Picks up lance						
Takes off cap						
Pricks finger						
Squeezes finger						
Picks up meter						
Collects blood						
Uses tissue						
Tidy up						

Score 1 for each sequence step completed independently

## Errors

Takes out more than one strip						
Forgets to close tub						
Puts wrong end of strip in meter						
Uses same finger as day before						
Pricks finger on tip rather than side						
Pulls finger away						
Does not squeeze enough blood						
Pulls strip out before reading shows						
Licks finger instead of using tissue						
Misses Finger						

Score 1 for each error made

## Supporting Diabetes Self-management in Persons with Cognitive Impairment after Acquired Brain Injury

**Background.** Individuals with cognitive impairment arising from acquired brain injury (ABI) are often supported to engage in diabetes self-management through the use of verbal guidance provided by carers. This disablement incurs burden and emotional strain for carers, and potential upset and embarrassment for individuals.

GUIDE, developed by O'Neill and Gillespie (2008) is an automated verbal prompting system which aims to replicate the verbal guidance often provided to individuals with cognitive impairment by carers. It has previously been shown to be effective in supporting individuals with cognitive impairment to don their prosthetic limbs and to engage in their morning routine.

**Aims.** The aim of this study is to investigate whether the GUIDE system can improve the ability of individuals with cognitive impairment to self-manage their diabetes.

**Methods.** Participants will be five to ten individuals recruited from two specialist brain injury rehabilitation units and a diabetes clinic in Glasgow, who have a diagnosis of diabetes and ABI. Informed consent will be sought from all participants capable of providing it; otherwise it will be sought from their legal guardian. Participants will complete a brief neuropsychological battery to establish a cognitive profile. The study will employ an ABA<sup>^</sup> design using multiple baseline Single Case Experimental Design (SCED) methodology.

**Applications.** It is possible that GUIDE could be used more widely to support individuals with cognitive impairment (e.g. dementia) in diabetes self-management and to support other complex behavioural sequences.

## **Introduction**

Many chronic medical conditions exist that require individuals to engage in medical self management in order to regulate them. Diabetes mellitus is one such condition which requires sufferers to self monitor their blood glucose levels and use this information to guide their behaviour with regard to food and liquid intake, exercise and insulin administration. The cognitive burden of engaging in blood glucose monitoring and planning future action can therefore be high requiring the individual to engage in complex sequencing behaviours.

Diabetes mellitus is often co morbid with other conditions which can impair cognition including vascular related cognitive impairment, mild cognitive impairment, traumatic brain injury and hypoglycaemic brain injury. Individuals with these conditions can often require a high degree of personal support in order to engage in diabetes self management and the costs of providing this level of support are not insignificant.

Individuals with cognitive impairment arising from acquired brain injury (ABI) are often supported to engage in diabetes self management through the use of scaffolding which refers to a process of providing verbal guidance during task performance (Sawyer, 2006). Scaffolding has been shown to be effective in reducing errors when learning a new skill when compared to supervised trial and error learning in a sample of individuals with cognitive impairment (Donaghey, McMillan & O'Neill, 2010). Although carer scaffolding can be effective, it may not always be an acceptable intervention to individuals with cognitive impairment who may feel upset and embarrassment as a result of a loss of independence which may in turn lead to emotional strain on carers. The use of an automated verbal scaffolding system may hence reduce carer burden and provide a more acceptable intervention for individuals.

GUIDE (General User Interface for Disorders of Execution) system was developed by O'Neill and Gillespie (2008) as an assistive technology for cognition (ATC) which aims to imitate the verbal guidance often provided to individuals with cognitive impairment by carers. The system prompts users, asks questions of users and accepts verbal responses ('yes' and 'no'). The system sequences complex tasks for users into steps and sub steps and asks a series of questions for each. In this manner a user can be guided through a complex sequence in a manner which simulates carer scaffolding of task performance.

Errorless learning has been defined as 'a learning condition that involves the minimisation of errors during the learning process' (Clare and Jones, 2008; p. 1). The concept was first introduced by Baddeley & Wilson (1994). They suggested that for people with memory impairment it may be important to restrict errors that occur during the learning process as priming and implicit memory may mean that once a mistake has been made, individuals with cognitive impairment may be more likely to make the same mistake again. They suggested that errorless learning may facilitate performance to a greater degree than trial and error methods in populations suffering cognitive impairment. Errorless learning principles have previously been applied in rehabilitation to practical tasks with success (Baddeley & Wilson, 1994; Clare et al., 2001) GUIDE can be conceptualised as an errorless learning approach as it prompts users before each action step thus minimising errors.

GUIDE has previously been shown to be effective in supporting individuals with cognitive impairment to don their prosthetic limbs (O'Neill et al. 2010). Use of the GUIDE system led to a reduction in safety critical errors and omitted steps when compared to baseline. It has also been found to be efficacious in supporting an individual to engage in their morning routine involving getting out of bed and engaging in personal care (O'Neill et al., 2013). Results showed that the GUIDE system significantly reduced the level of carer

prompting required and the number of errors made in both an in-patient setting and in the participants own home.

The current study aims to investigate whether GUIDE can be used to support individuals with diabetes mellitus and co-morbid acquired brain injury to engage in diabetes self management, a complex self care sequence where they are otherwise incapable of doing so independently due to cognitive impairment.

## **Aims and Hypotheses**

### *Aims*

To investigate whether an auditory verbal prompting system (GUIDE) can facilitate diabetes self management in individuals with diabetes mellitus and co-morbid cognitive impairment.

### *Hypotheses*

Use of the GUIDE system will produce significant performance improvements compared to baseline.

## **Plan of Investigation**

### *Participants*

Participants will be individuals with a diagnosis of diabetes mellitus and co-morbid cognitive impairment, who as a result of their cognitive impairment have difficulty self managing their diabetes. It is estimated that between five and ten participants will be recruited. Participants will be recruited from Graham Anderson House (GAH; a specialist neurobehavioural assessment and post-acute rehabilitation hospital for people with a non-progressive acquired brain injury) where it is estimated that 10% of annual admissions have co-morbid diabetes which they require significant support in managing. Participants will also be recruited from the Huntercombe Brain Injury Rehabilitation Centre in Murdostoun.

### *Inclusion and Exclusion Criteria*

#### Inclusion

- Participants must have cognitive impairment.
- Participants should be able to carry out diabetes self management without errors or omissions when provided with verbal prompts from nursing staff.
- Participants must have been identified as having difficulty independently carrying out diabetes self management
- Participants must be English speaking (as prompts will be provided in English).

#### Exclusion

- A level of cognitive impairment that would prevent individuals from being able to follow and implement verbal prompts.
- Individuals who can safely carry out diabetes self management without support.

### *Recruitment Procedures*

Informed consent will be sought from all participants capable of providing it. Where participants lack capacity, consent will be sought from their legal guardian.

### *Measures*

The cognitive profile of participants will be established by administering the following brief neuropsychological test battery:

- Galveston Orientation and Amnesia Test (GOAT; Levin, O'Donnell & Grossman, 1979) – Measures experience of self and time functions.
- Hospital Anxiety and Depression Scales (HADS; Zigmond & Snaith, 1983) - assesses emotional functions.

- List Learning and Complex Figure Test from the BIRT Memory And Information Processing Battery (BMIPB; Coughlan, Oddy & Crawford, 2007) – as a measure of memory.
- Behavioural Assessment of Dysexecutive Syndrome (BADS; Wilsom, Alderman, Burgess, Emslie & Evans, 1996) – as a measure of higher-level cognitive functions.
- Test of Everyday Attention (TEA; Robertson, Ward, Ridgeway & Nimmo-Smith, 1994) – assesses attention functions.
- Test of Premorbid Functioning - UK Version (TOPF UK; Wechsler, 2011)

Outcome of the intervention will be determined through the use of two measures. The first outcome measure will allow for the recording of the number of sequencing errors made by participants in baseline, intervention and return to baseline phases and the number of prompts required by nursing or support staff to ensure sequence performance. The second measure of outcome will consist of a rating of participant satisfaction with the intervention following each trial.

### *Design*

A series of between five and ten single-participant investigations will be conducted using Single Case Experimental Design (SCED) methodology with a multiple baseline across subjects design. The aim of the current study is to produce reliable improvement in diabetes self management in individuals with diabetes mellitus and co-morbid cognitive impairment. Depending on their level of cognitive impairment some participants may be expected to retain gains once the GUIDE system is removed, therefore a 'return to baseline' phase will also be employed to identify whether participants retain gains after the removal of the intervention.



In a multiple baseline across subjects design a single transition from baseline to treatment (AB) is instigated at a different time to each subject according to a planned staggered sequence rather than introducing the intervention to all participants at the same time. The staggered initiation of the intervention makes it implausible that behaviour change has been caused by some extraneous variable. Barlow and colleagues (2009) identified that this type of design has high internal validity and allows for greater experimental control as behavior changes for each subject only after the intervention has been implemented.

### *Research Procedures*

Currently individuals at GAH are supported to perform diabetes self-management through prompts from nursing staff or rehabilitation support workers. Programming the GUIDE system to support individuals through diabetes self management would consist of a number of steps. Firstly the problem space would need to be defined. This would involve observation of a Diabetes Specialist Nurse supporting an individual with acquired brain injury through diabetes self-management. This process would be video recorded and the dialogue analysed in order to develop a protocol of the steps involved, the prompts given and the questions used to effect accurate sequence performance.

This protocol will then be used to map the problem space of the task using the GUIDE system. A series of prompts relating to one action at a time are entered into the system in order to elicit the desired sequence of behaviours which will lead to successful task performance. The GUIDE system attempts to simulate the scaffolding support provided by carers by modelling prompts on those provided by carers. These prompts will generally be in the form of questions to the user and will require a verbal response from them. Checks for any anticipated mistakes or deviations from the desired sequence are also

programmed into the GUIDE system. Prompts may be tailored to the individual user if necessary.

During baseline participants will be provided with verbal prompts by nursing staff in order to enable them to engage in diabetes management. Prior to the intervention phase, participants will be trained briefly in the use of the GUIDE system and voice recognition software. During the intervention phase, the GUIDE system will be set to verbally prompt participants that it time to engage in diabetes self-management. At these times the GUIDE system will prompt the participant through the task; however a nurse will be present in order to correct any safety-critical errors or omissions that might occur. In the return to baseline phase, participants will again be provided with verbal prompts by nursing staff in order to enable them to engage in diabetes management. Data in all phases will be recorded through video recording of participants on task behaviour.

### *Data Analysis*

There are numerous statistical techniques that have been identified as suitable for use in studies employing SCED. But to date no single best method has been identified for the analysis of such data (Parker & Vannest, 2009; Parker, Vannest & Davis, 2011; Ma, 2006; Solanas, Manolov & Onghena, 2010). Manolov and colleagues (2011) attempted to bring some clarity to this by comparing the effectiveness of four of these methods for estimating intervention effect. The authors concluded that data characteristics are vital for choosing an appropriate analysis procedure and therefore recommended visual inspection of data in order to inform selection of an appropriate analysis procedure. Barnett and colleagues (2012) also recommended employing visual analysis of graphed data along with statistical analysis in order to draw informed conclusions about intervention effectiveness when using SCED methodology. An appropriate data analysis procedure will therefore be selected

following visual inspection of collected data according to the procedures outlined by Manolov and colleagues (2011). Procedures employed may include Improvement rate difference (IRD; Parker et al., 2009), nonoverlap of all pairs (NAP; Parker & Vannest, 2009) and slope and level change (SLC; Solanas et al., 2010). Manolov and colleagues (2011) that IRD may be useful for data with no quadratic or linear trend and no autocorrelation or heteroscedasticity. They suggested that NAP (with correction for linear trend) and SLC can be used where autocorrelation or heteroscedasticity are present.

### *Justification of Sample Size*

The randomised controlled trial (RCT) is widely considered to be the gold standard of research designs, providing the best evidence of intervention effectiveness (Sackett et al, 1996). While RCTs can reduce bias in studies through randomisation and blinding, they can also be costly and time consuming and due to their rigor may lack generalisability. In the field of rehabilitation, many interventions are by necessity highly individualised, meaning that an RCT design may be inappropriate. The protocol of the current study may need to be individualised for participants, for example in order to reflect differing levels of cognitive ability and where different equipment is being used. RCTs also require large sample sizes in order for randomisation procedures to be effective which may not be feasible to achieve in rehabilitation research. The target population of the current study is very specific and it would likely be impossible to recruit sufficient numbers to utilise an RCT design.

Single case experimental designs (SCED) have been referred to as being ‘the most effective and powerful’ nonrandomised experimental designs (Shadish, Cook, & Campbell, 2001; p. 171). Barnett and colleagues (2012) advocated that SCED are better suited than RCTs for studies in which changing patient behaviour and functional status are the primary goals and targeted sample sizes are less than 10. For these reasons the SCED would seem

the most appropriate for the current study and a sample size of between five and ten individuals would seem a reasonable target for this type of design.

### *Settings and Equipment*

Participants will be tested in the base of the organisation from which they were recruited.

Equipment required includes the following:

6. Johnson & Johnson Accu-Check blood glucose monitoring device
7. Hardware – A PC with Windows XP to run the GUIDE software program and additional hardware to enable audio presentation to the user and verbal responses from the user to be received. This will consist of either an array microphone and speaker or a wireless headset with earphones and microphone
8. Voice Recognition Software – this is needed in order for the GUIDE system to receive verbal input from the participant. The Dragon Naturally Speaking 9.5 software will be used.
9. Protocol – the protocol consists of a sequence of steps and checks which can enable users to successfully complete diabetes self management. This will be developed through consultation with specialist diabetes nursing staff and through observation of individuals being prompted through diabetes self management by nursing staff or rehabilitation support workers
10. GUIDE software program – GUIDE is a specially designed software program which can receive input from the voice recognition program and use this to trigger a response to user input including the provision of prompts or asking questions of the user based on the inputted protocol.
11. Video camera

## **Health and Safety Issues**

### *Researcher Safety Issues*

None identified. GUIDE trials will be carried out by nursing staff.

### *Participant Safety Issues*

Use of blood glucose monitoring equipment by individuals with cognitive impairment is a potential risk. Supervision will be provided by qualified nursing staff at all times during intervention in order to prevent safety critical errors and ensure participant safety.

Further details of Health and Safety issues can be found in the appendices (see Appendix A)

## **Ethical Issues (including where submissions will be made)**

Memory impairment and executive dysfunction are common in individuals with brain injury meaning that they may lack the capacity to consent to participating in research. Due to their level of cognitive impairment, these individuals stand to have the most to gain from the current intervention, therefore to exclude them due to a lack of capacity may disadvantage them compared to those who have capacity. Ethical approval will therefore be sought from the Scotland A Research Ethics Committee.

## **Financial Issues**

- The use of a University of Glasgow encrypted laptop would be required.
- GUIDE software to be provided free of charge by the field supervisor's organisation.
- Dragon Naturally Speaking 9.5 voice activation software will be required.

Full details of expenses are included in the appendices (see Appendix B).

## **Timetable**

It is envisaged that ethical approval will be sought in December 2013 and that recruitment and investigation will commence in January 2014 (see Appendix C).

### **Practical Applications**

The practical applications of GUIDE are potentially wide. It is possible that GUIDE could be used more widely to support individuals with cognitive impairment (e.g. dementia) in diabetes self-management. GUIDE could also be used to support other complex behavioural sequences that are generally verbally augmented by carers.

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