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Evaluating the Intervention Fidelity of Self-managed Computer Therapy for Aphasia Post-stroke

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Abstract

Introduction: Intervention fidelity refers to whether an intervention is delivered as intended by the designer, which can affect intervention success. This study aimed to evaluate fidelity to the StepByStep approach to aphasia computer therapy delivered in the Big CACTUS trial.

Methods: A mixed methods approach was adopted comprising five interrelated studies. Firstly, a narrative literature review explored the methods used in fidelity evaluation in stroke rehabilitation research. Secondly, a qualitative interview study with StepByStep approach experts identified the key components of the intervention delivered in the Big CACTUS trial. Both of these studies informed the data to be collected in the third study, a process evaluation of intervention fidelity in the Big CACTUS trial. The fourth study explored the factors associated with adherence to computer therapy practice through secondary analysis of trial data and qualitative interviews with people with aphasia (PWA) and their carers who had used the computer therapy in the trial. The final study identified 'essential' components of the intervention associated with improved word-finding in the Big CACTUS trial.

Results: Key informants identified four key components of the StepByStep approach: the StepByStep software, therapy set-up (tailoring and personalising), regular independent practice, and supporting and monitoring use. All components of the intervention were delivered with moderate to high fidelity in the Big CACTUS trial. Factors associated with increased adherence to independent practice included: the PWA having had their stroke longer ago; the PWA's perceived and actual capability to engage with computer therapy; having the opportunity to carry out practice, which was aided by having the computer therapy for longer; having more input from a speech and language therapist; and a number of motivational factors. Exploratory data analysis indicated that the components of the intervention associated with change in word-finding ability were: rigorous tailoring of the computer therapy exercises and spending more time on naming words in functional sentences exercises.

Conclusion: The StepByStep approach was delivered with moderate to high fidelity. This study has informed the interpretation of trial results, recommendations for clinicians delivering the intervention in clinical practice and will inform further intervention refinement.

List of Abbreviations

Big CACTUS A study to assess the clinical and cost effectiveness of aphasia computer treatment versus usual stimulation or attention control long term post stroke

CAT Comprehensive Aphasia Test

CFIF Conceptual Framework for Implementation Fidelity

CINAHL Cumulative Index to Nursing and Allied Health Literature

COAST Communication Outcome after Stroke

COM-B Capability, Opportunity, Motivation – Behaviour model

CST Consent Support Tool

HA High adherer

ISRCTN International Standard Registered Clinical/sociAl sTudy Number

LA Low adherer

M Mean

MA Moderate adherer

MEDLINE Medical Literature Analysis and Retrieval System Online

MRC Medical Research Council

N/A Not applicable

NHS National Health Service

NIH-BCC National Institute for Health Behaviour Change Consortium

PDCA Plan-Do-Check-Action

PI Principal investigator

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PWA Person with aphasia

RCT Randomised Controlled Trial

REC Research Ethics Committee

SD Standard Deviation

SLT Speech and Language Therapy/Therapist (also referred to as therapists)

TDF Theoretical Domains Framework

TOMs Therapy Outcome Measures

UK United Kingdom

WAI Working Alliance Inventory

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Chapter One: Background

This thesis investigates the intervention fidelity with which the StepByStep approach to aphasia computer therapy was delivered and received within the Big CACTUS randomised controlled trial (RCT). The Big CACTUS trial investigated the clinical and cost effectiveness of aphasia computer therapy versus usual stimulation or attention control in the long-term post-stroke (Palmer et al, 2019). This introductory chapter provides the background for the study including an overview of fidelity, aphasia, aphasia computer therapy and more specifically the development of the StepByStep approach to aphasia computer therapy and the Big CACTUS trial in which it has been evaluated. This will be followed by the aims and objectives of this doctoral thesis and conclude with discussion of the methodological approach underpinning the thesis as a whole.

1.1 FIDELITY

Fidelity refers to the degree to which an intervention is implemented as intended by the designer or investigator (Carroll et al, 2007). Therefore, fidelity is a potential moderator of the relationship between an intervention and its intended outcome (Dusenbury et al, 2003). Methodological strategies used to monitor and enhance fidelity can increase the reliability and validity of intervention studies (Bellg et al, 2004). Furthermore, detailed reporting of how an intervention was implemented within a research context can aid replication and therefore facilitate implementation into clinical practice (Walker et al, 2017). One of the challenges in evaluating fidelity is the lack of a single unifying term (Gearing et al, 2011). The terms commonly used include: treatment fidelity (Moncher & Prinz, 1991), intervention fidelity (Nelson et al, 2012), implementation fidelity (Carroll et al, 2007) and treatment integrity (Yeaton & Sechrest, 1981). For the purpose of this thesis I will use the term *intervention fidelity* because it is the most all encompassing term. *Fidelity* is a more comprehensive term than integrity (i.e. includes provider training and treatment receipt; Bellg et al, 2004) and the term *intervention* incorporates both medical and behavioural interventions across all stages of the research process from efficacy studies to implementation.

The importance of evaluating fidelity

The origins of fidelity enhancement and evaluation stem from efficacy studies in the field of psychotherapy, which recognised the importance of tightly controlling and measuring intervention delivery to increase the internal validity of the study (Lichstein et al, 1994). Without evidence of intervention fidelity, it is not possible to know whether an outcome is the result of the intended intervention (Moncher & Prinz, 1991). For example, if a significant result was found, but fidelity was not measured, this could have been the result of an effective intervention or an unknown contaminant added to the intervention (Moncher & Prinz, 1991). Conversely, a non-significant result in the absence of fidelity evaluation could have been the result of an ineffective intervention, or the intervention not having been delivered as intended (Yeaton & Sechrest, 1981). The failure to deliver an intervention as planned is known as a type III error (Dobson & Cook, 1980).

Despite the impact of failing to evaluate fidelity, it remains a neglected aspect of trial design (Walker et al, 2017). This might be due to a lack of consensus around the definition and construct of fidelity both between and within disciplines (Gearing et al, 2011). Reviews in various fields, including social work (Naleppa & Cagle, 2010), diabetes self-management (Schinckus et al, 2014), and aphasia (Brogan et al, 2019), have established that fidelity remains largely under-investigated demonstrating the widespread nature of this methodological challenge. A study examining the barriers to fidelity processes found that whilst researchers in the field of psychotherapy appreciated the importance of fidelity, the lack of general knowledge, theory and guidelines, as well as the time and costs involved were all significant barriers (Perepletchikova et al, 2009). Schoenwald et al (2011) established researcher's choice of measurement method was often dependent on the availability of resources with direct observation perceived to be most effective, but self-reported measures thought to be more efficient.

Reporting of intervention description has been criticised for many years (Altman, 1995; Walker et al, 2017) with some suggesting that this is due in part to the lack of editorial requirement to provide detailed information about the interventions intended and actual delivery (Perepletchikova et al, 2009). There is however growing recognition of the importance of providing a thorough description of an intervention; this has been demonstrated through the development of a Template for Intervention Description and Replication (TIDieR) to be used alongside the CONSORT statement for RCTs (Hoffmann et al, 2014). Two items on the TIDieR checklist directly relate to fidelity; the first asks how well any assessments or strategies to maintain or enhance fidelity were planned, whereas the second asks how well it was actually delivered (e.g. did the strategies work?) and to what

extent it was delivered as planned (Hoffmann et al, 2014). However, a recent review found that even if all information recommended by the TIDieR checklist is provided, studies still do not provide sufficient information to enable clinical replicability of rehabilitation interventions (Negrini et al, 2019). Recent consensus-based recommendations from the field of stroke rehabilitation suggest that the development, monitoring and reporting of interventions needs to be improved. In relation to monitoring it suggests that, in addition to the information indicated by the TIDieR checklist, the method for measuring fidelity should be trial and intervention-specific, and information about provider training and competence should be reported (Walker et al, 2017).

Fidelity evaluation and measurement

According to the MRC complex intervention guidance evaluating fidelity is essential at all stages of the intervention development and evaluation process, although the purpose and extent of the evaluation might vary (Craig et al, 2008). Explanatory research aims to establish whether an intervention is efficacious for a specific group of people in tightly controlled or 'ideal' conditions, by asking 'can it work?' (Zwarenstein et al, 2008). In an explanatory context fidelity evaluation is likely to be detailed, resource intensive and the results of any evaluation are likely to inform strategies to enhance fidelity to the intervention (Miller & Rollnick, 2014). In contrast, pragmatic trials aim to establish the effectiveness of an intervention if it were implemented in clinical practice with a more inclusive sample and multiple providers, by asking 'does it work when delivered in usual practice?' This can often result in a more flexible application of the intervention (Zwarenstein et al, 2008). In this context researchers are aiming to have minimal effect on the intervention to enhance the external validity of the research. Consequently, fidelity evaluations carried out alongside pragmatic trials can illuminate how interventions would be delivered in a real-world context. So whilst fidelity enhancement and evaluation remains important, it is essential that strategies to enhance fidelity, such as provider training and relaying findings from fidelity evaluation back to the providers, do not go beyond that which can be delivered in clinical practice outside of a trial (Miller & Rollnick, 2014). The method of fidelity evaluation should also be designed to have minimal impact on the intervention. For example, direct or video observation could be inappropriate because it might create an artificial setting that would not occur in clinical practice. It has been suggested that fidelity evaluation should continue when the intervention is implemented more widely, outside of a research study, since at this point the flexibility with which an intervention is delivered can increase exponentially as there are no longer the controls in place that research provides (Schoenwald et al, 2011).

A widely accepted, one size fits all fidelity measure does not exist and is unlikely to be developed due to the diverse nature of interventions both within and between health conditions. Some interventions (e.g. Cognitive Behavioural Therapy) and some conditions (e.g. psychosis) have a wide variety of pre-existing fidelity measures to draw upon (Fowler et al, 2011). For those interventions for which no existing tool exists it can be time consuming and costly to develop an applicable fidelity evaluation method. However, if no tool exists and a new tool needs to be developed the next question is 'what should be measured?' The two primary considerations at this stage include: 1) which elements of fidelity need to be measured? (relevant fidelity frameworks should be consulted), and 2) which aspects of the intervention are most important to measure? The elements of fidelity will be discussed in the next section (below). Varied approaches to defining the aspects of the intervention that require measurement have been proposed. Mowbray et al (2003) propose measuring structural and procedural fidelity criteria. Hawe et al (2004) suggest fidelity should be defined by its function rather than by its components, to account for adaptation. Abry et al (2015) propose measuring the active ingredients of the intervention. Nelson et al (2012) suggest measuring the intervention components identified by the intervention's theory of change. The common thread amid these approaches is the aim to identify and measure fidelity to intervention-specific components hypothesised to contribute to achieving the desired outcome. For the purpose of this thesis I will refer to them as *key components* of the intervention.

Historical overview of fidelity and fidelity frameworks

The concept of establishing whether an intervention was delivered as intended was initially described as treatment integrity (Yeaton & Sechrest, 1981) before the term treatment fidelity was coined (Moncher & Prinz, 1991). At this point it was also proposed that the concept of treatment fidelity should include *treatment differentiation*, whether there is sufficient difference between the intervention and the control condition (Moncher & Prinz, 1991). Subsequently practitioner competence and skill were purported to be elements of fidelity (Waltz et al, 1993). Up until this time fidelity evaluation focused solely on the practitioner. However, Lichstein and colleagues (1994) proposed that it was not only the behaviour of the practitioner, but also the behaviour of the person receiving the intervention that must be considered. The process of receiving the intervention was divided into *intervention receipt*, whether the participant comprehended the intervention, and *intervention enactment*, whether they engaged with the treatment outside of the delivered session (Lichstein et al, 1994). The Treatment Fidelity Workgroup of the National Institute of Health Behaviour Change

Consortium (NIH-BCC) developed a model incorporating all of the above aspects of fidelity (Bellg et al, 2004). The NIH-BCC fidelity framework includes study design, provider training, treatment delivery, treatment receipt and enactment of treatment skills and makes a series of recommendations for enhancing and monitoring the reliability and validity of the intervention. In this model, 'study design' refers to ensuring equivalent treatment dose within and across trial conditions and having plans for implementation setbacks primarily through strategies to enhance fidelity. The body of research depicted in figure 1.1 emerged from intervention studies in the fields of psychology and psychiatry. These fields have typically used explanatory trials to establish the efficacy of interventions, whereas research from a sociological perspective has focused more widely on the fidelity of intervention implementation in a variety of different contexts.

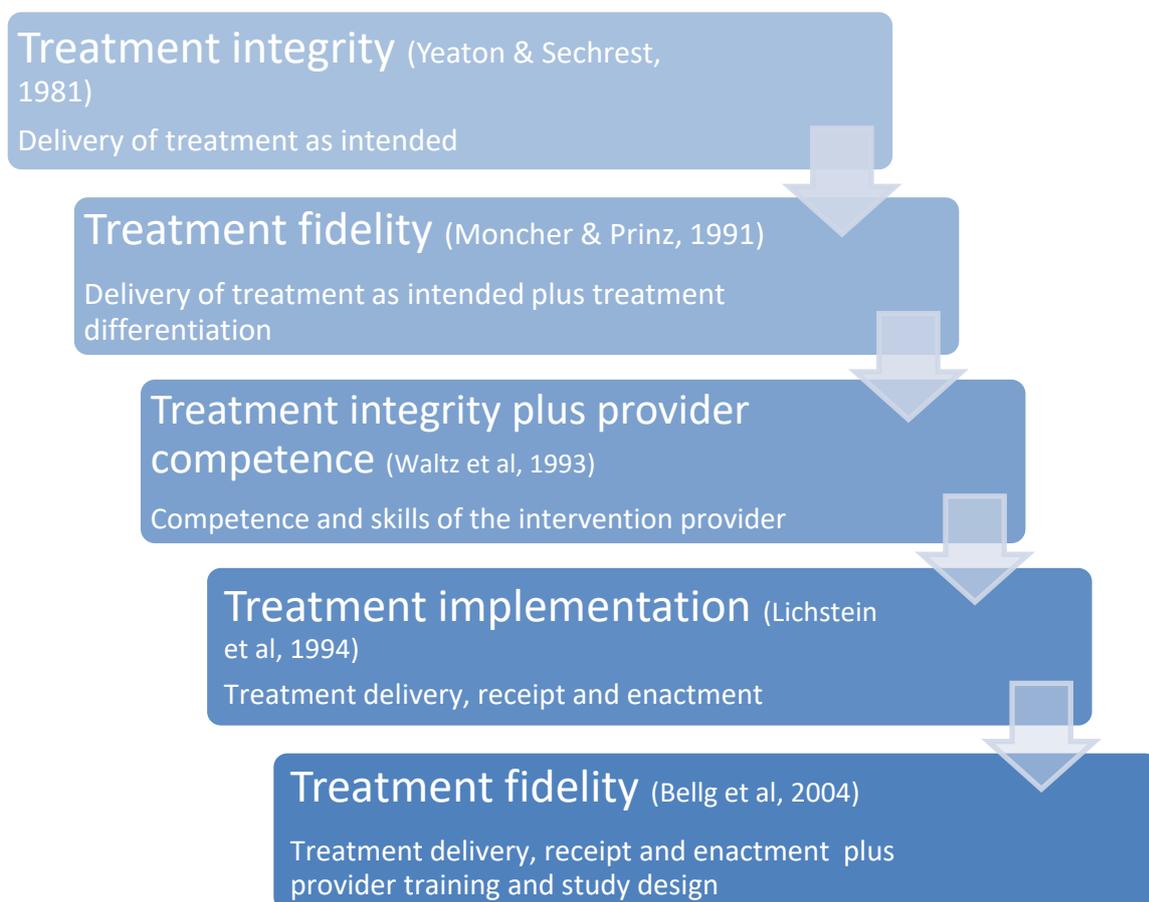


Figure 1.1. The development of the concept of treatment fidelity from the field of psychology and behaviour change research

One of the most frequently cited frameworks from the implementation literature is the Conceptual Framework for Implementation Fidelity (CFIF; Carroll et al, 2007). The framework is based on a literature review, which highlighted the key elements of fidelity and concluded that previous theory and research failed to explore relationships between the different elements of fidelity. The CFIF divides the elements of fidelity into three broad categories of 1) adherence, 2) moderators of adherence and 3) identification of essential components (see figure 1.2; Carroll et al, 2007). The aspects of adherence that must be measured in order to evaluate fidelity are referred to as content (i.e. adherence to the key components of the intervention), frequency, duration and coverage of the intervention (i.e. dose). These core elements are distinguished from other elements that are thought to moderate fidelity: quality of delivery (i.e. the manner in which the provider delivers an intervention, including provider competence and skill), participant responsiveness (i.e. participants willingness to engage with the intervention based on the acceptability of the intervention), comprehensiveness of intervention description (i.e. clearly defined intervention components) and strategies to facilitate implementation (e.g. training).

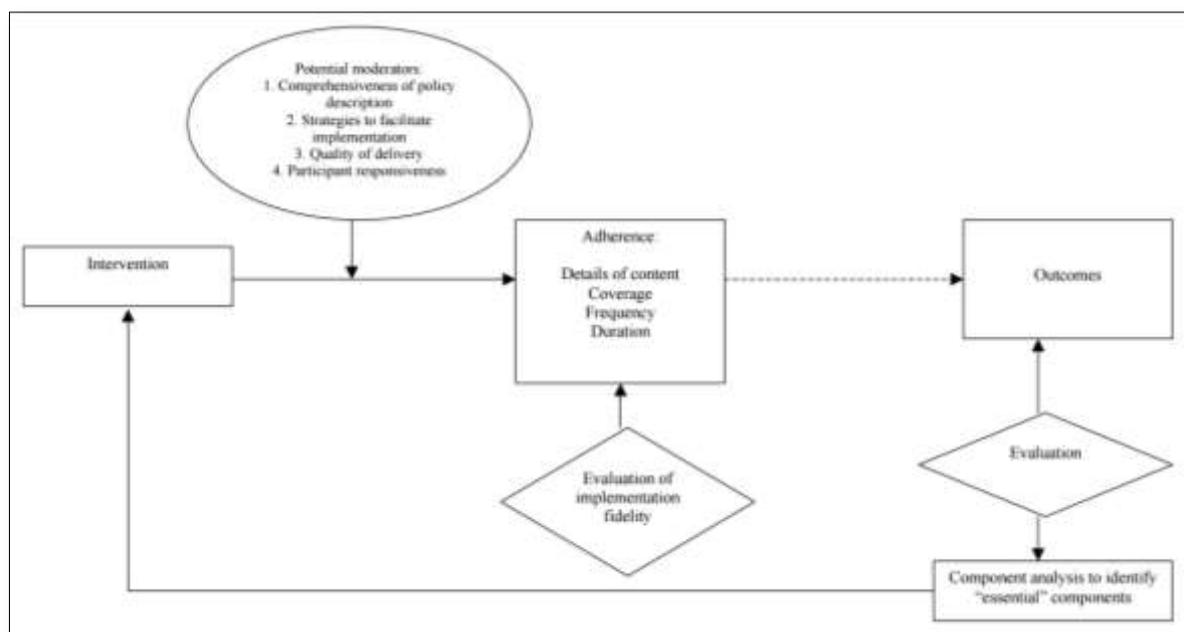


Figure 1.2. Conceptual Framework for Implementation Fidelity (Carroll et al, 2007; licenced under CC BY 4.0; reproduced with no changes)

Carroll et al (2007) suggest that programme differentiation (i.e. identifying the key components of the intervention and how it is different to other interventions or the comparison condition), whilst a relevant concept, is distinct from fidelity. In the CFIF aspects of programme differentiation are divided across two elements: *comprehensiveness of policy description*, a moderator of adherence that can be assessed, and *component analysis to identify essential components*, a discrete aspect of the framework that needs to be informed by the outcomes of prior studies within an iterative implementation process (Carroll et al, 2007). Multiple modifications have been suggested by other researchers including the addition of context and recruitment as additional moderating factors (Hasson, 2010) and a cycle of learning effects running throughout the implementation process (Masterson-Algar et al, 2014). The strength of the CFIF is that it acknowledges that the elements of fidelity are not discrete and considers how the different elements interact with one another (see figure 1.2) whilst still including all elements of the NIH-BCC framework (Bellg et al, 2004), albeit using different terminology. As a result, the CFIF was chosen to inform the evaluation of intervention fidelity described within this thesis.

1.2 APHASIA

Aphasia is an acquired communication disorder, affecting the production or comprehension of verbal language and the ability to read or write. Approximately one third of stroke survivors experience aphasia (Engelter et al, 2006). Aphasia reduces social participation impacting on all aspects of life including domestic life, employment and relationships with family and friends (Dalemans et al, 2008). Speech and language therapy (SLT) for people with aphasia (PWA) aims to improve the ability to communicate and participate in everyday activities by directly addressing specific language impairments or by teaching strategies that compensate for the impairment. The most recent Cochrane Review for aphasia found evidence of the effectiveness of SLT compared to no treatment, but there is no evidence that one treatment was more effective than another (Brady et al, 2016).

Neuroplasticity is the ability of the brain to change and develop neural pathways and synapses throughout an individual's life (Draganski et al, 2004). Following a stroke, this enables skills such as language to be re-learned. Impairment based SLT aims to promote neuroplasticity for language. Kleim and Jones (2008) theorised a number of key principles underpinning experience dependent neuroplasticity including: 'use it or lose it', 'use it and improve it', specificity matters (the nature of the therapy dictates the nature of plasticity), salience matters (the training experience must be sufficiently salient to induce plasticity),

repetition matters (sufficient repetition is required to induce plasticity) and intensity matters (sufficient training intensity is required to induce plasticity).

The Cochrane review of aphasia therapy indicated that therapies that were delivered more intensively, at a higher dose or for a longer duration were more effective (Brady et al, 2016). There is ongoing debate regarding whether it is the total dose or intensity of therapy that enables SLT to be most effective. A highly cited review by Bhogal et al (2003) found intense therapy over a short time improves therapy outcomes (average of 9 hours per week for 11 weeks in positive studies versus 2 hours per week over 23 weeks in negative studies). Recent opinion (Doogan et al, 2018) suggests we should instead focus on Bhogal et al's (2003) other finding that a greater total amount of therapy (98 hours versus 44 hours) was associated with improved outcomes. The intensity versus dose controversy is underpinned by the two conflicting principles of massed (Pulvermüller & Berthier, 2008) and distributed practice (Dignam et al, 2015); some suggest that intensive or massed practice results only in an improvement in short-term performance, whereas distributed practice (i.e. similar dose delivered over a longer period) facilitates long-term learning of skills or information (Soderstrom & Bjork, 2015). Dignam et al (2015) explored the difference between intensive (16 hours per week for three weeks) and distributed (six hours per week for eight weeks) aphasia therapy. The intervention included computer therapy, group-based therapy and one-to-one impairment and functional therapy. Distributed therapy resulted in greater improvement on a naming test when compared with intensive therapy, but there was no difference between distributed and intensive therapy on measures of communicative effectiveness, communication confidence or quality of life (Dignam et al, 2015). Doogan et al (2018) propose distributed practice may be necessary for long-term therapeutic gains. However, it is important to note that both high intensity and high dose therapies were associated with higher attrition in the Cochrane review of aphasia therapy, suggesting these interventions may not be acceptable to all (Brady et al, 2016).

1.3 FIDELITY IN APHASIA RESEARCH

Prior to commencement of this PhD in 2014, there was limited engagement with the concept of fidelity in aphasia research. A review by Hinckley and Douglas (2013) found that only 14% (21/149) of aphasia treatment studies published over a ten year period in three SLT journals reported on the fidelity of the intervention. Thirteen studies checked adherence to the treatment protocol (by rating a sample of video recorded sessions and recording the percentage of treatment steps completed), five of the studies described direct observation during treatment sessions, two studies used a therapy manual and one described provider

training. A more recent systematic review (Brogan et al, 2019) investigating the reporting of treatment fidelity processes in RCTs of impairment-based therapy for post-stroke aphasia found that 90% (38/42) reported some aspect of fidelity, be that a method of evaluation or strategy to enhance fidelity. However, of these only 21% (9/42) explicitly reported fidelity processes. Fidelity processes were categorised using the NIH-BCC fidelity framework (Bellg et al, 2004). Therapy dosage was the most commonly described fidelity component (37/42), whereas treatment enactment (ensuring participants use the skills from therapy in everyday life) was the least commonly addressed element of fidelity (2/42). The methods used to evaluate fidelity were not reported in the review (Brogan et al, 2019). Whilst direct comparison between the two reviews cannot be made due to different inclusion criteria (all designs of treatment studies versus only RCTs) and data extracted (method versus element of fidelity) it does appear to indicate a positive trend to suggest that more aphasia treatment studies are including fidelity processes (Hinkley & Douglas, 2013; Brogan et al, 2019).

Several articles with a focus on evaluating fidelity in aphasia research were beyond the scope of, or published after, Brogan and colleagues (2019) review. Three small-scale studies have been published focussing on fidelity assessment in aphasia therapy interventions, including: motivational interviewing to prevent depression for PWA (Holland et al, 2018; three participants), computer aphasia therapy (Ball et al, 2018; four participants) and Better Conversations with Aphasia (Heilemann et al, 2014; seven participants). All studies used video recordings of the therapy and evaluated all recorded sessions. Heilemann and colleagues (2014) based their evaluation on the elements of the CFIF (Carroll et al, 2007), which included designing an intervention-specific tool to determine adherence to dose and content, as well as quality of delivery. Holland et al (2018) referenced the NIH-BCC fidelity framework (Bellg et al, 2004) and used a pre-existing fidelity assessment specific to motivational interviewing. Ball et al (2018) did not refer to a fidelity framework and the measure of fidelity was not described other than a footnote in a results table stating that participants 'displayed expected use of icons during practice'. The authors acknowledged the presence of a researcher filming the computer aphasia therapy as a limitation, however they perceived observation was essential to determine how participants practised in order to identify behavioural units of relevance (Ball et al, 2018). Whilst this might be relevant during intervention development, an iterative fidelity evaluation with no standardised measure of fidelity, as described by Ball et al (2018), would be difficult with a larger trial design in which multiple sites deliver and measure the same intervention.

Carragher et al (2019) published a fidelity protocol for the on-going Action Success Knowledge trial investigating the effectiveness of a psychosocial intervention to prevent depression in PWA. The fidelity evaluation was designed using the NIH-BCC fidelity

framework (Bellg et al, 2004) and fidelity processes are described in relation to each of the five fidelity elements, however the novel tool developed to measure fidelity will only evaluate adherence to the content of the components, competency skills and the overall quality of delivery. All sessions will be audio/video recorded with plans to evaluate the first goal setting session and therapy session from each therapist, with later sessions selected for fidelity checking at random, if resources allow. Therapists will receive feedback based on the results of the monitoring to enhance the fidelity of the intervention. It is unclear whether this is an aspect of the intervention that would be delivered in clinical practice (Carragher et al, 2019) and equally unclear whether the main trial is intended to be pragmatic or explanatory (Worrall et al, 2016).

Both the reviews (Hinkley & Douglas, 2013; Brogan et al, 2019), as well as the primary (Ball et al, 2018; Holland et al, 2018; Heilemann et al, 2014) and planned research (Carragher et al, 2019) demonstrate that the importance of fidelity evaluation is starting to be recognised in aphasia research. However, understanding of how fidelity should be measured and when and how fidelity should be enhanced would benefit from further discussion within the aphasia research community.

1.4 APHASIA COMPUTER THERAPY

PWA can continue to recover long after they have had a stroke (Allen et al, 2012). However, due to health care costs limited speech and language therapy is provided beyond the first few months post-stroke (Palmer et al, 2018). Computerised speech and language therapy is thought to be a cost-effective solution to provide therapy in the longer term as it provides maximum opportunity for practice with less SLT input (Zheng et al, 2016).

A systematic review found computer therapy is effective when compared to no therapy; additionally, there was some evidence that computer therapy may be as effective as clinician delivered therapy for some PWA (Zheng et al, 2016). The quality of evidence was deemed to be low due to the small number of studies (n=7) included in the review. Another review of technology for the treatment of anomia (a type of aphasia resulting in word-finding difficulties) that included more studies (n=23) also found that technology-based treatment improved naming of trained items (Lavoie et al, 2017). The review concluded that future research needs to evaluate whether improved naming generalises to the words being retrieved in everyday communication (Lavoie et al, 2017).

Recent primary research has continued to support the findings of the above review. A quasi-randomised feasibility study established word-finding therapy can be delivered remotely with

high fidelity and have the same treatment outcomes (improved picture naming, but not naming in conversations) as face-to-face therapy (Woolf et al, 2016). A cross-over design found app-based language therapy improved untrained picture naming and picture description (Stark & Warburton, 2018). Another quasi-randomised study investigated the impact of daily language stimulation from a support worker delivered in a virtual reality platform called EVA park (Marshall et al, 2016). The majority of participants adhered to the intervention and it was associated with improved functional communication; however, other treatment outcomes, including improved communicative confidence and reduced social isolation, were not achieved. All of the studies described had a sample size within the range of seven (Stark & Warburton, 2016) to 21 (Woolf et al, 2016) and none used a RCT design. The summary of primary research demonstrates varied use of computer therapy, with the technology either being the therapy platform itself (Stark & Warburton, 2018), the means of accessing the therapist (Woolf et al, 2016) or a combined approach (Marshall et al, 2016). The next section will describe the development and evaluation of one particular intervention, the StepByStep approach to aphasia therapy, which is the focus of this thesis.

1.5 THE STEPBYSTEP APPROACH TO APHASIA COMPUTER THERAPY

The StepByStep approach is a complex intervention aiming to improve word-finding (a common difficulty for PWA) that has been developed, refined and evaluated for more than fifteen years. According to the MRC guidelines, the dimensions of a complex intervention include the number of interacting components, the number of behaviours required by those delivering and receiving the intervention and the degree of flexibility and tailoring of the intervention permitted (Craig et al, 2008). One might assume that computer aphasia therapy is a standalone intervention that could be handed over to a PWA and that is all that is required. However, the StepByStep approach requires the vocabulary within the computer therapy software to be personalised and the exercises tailored to the individual's impairment as well as the provision of on-going support in order to enable the PWA to carry out independent practice (Palmer & Mortley, 2011). The various components of the intervention have been delivered by different people (SLTs, SLT assistants or volunteers) and through different delivery methods (remote or face-to-face) in different studies (Mortley et al, 2004; Palmer et al, 2012; Palmer et al, 2019). The intervention will be described in detail starting with the theoretical underpinnings, followed by studies describing the development and evaluation of the StepByStep approach to date and concluding with information about the Big CACTUS trial within which the StepByStep approach was evaluated.

Theoretical underpinnings of the StepByStep approach

The StepByStep approach has been developed based on current theory and evidence underpinning language therapy, as well as the perspectives of PWA (Palmer & Mortley, 2011). However, different theories are referenced across different publications as evidence has emerged and academic debate evolved. The key theory underpinning the potential for language recovery, and therefore the StepByStep approach, is neuroplasticity, which refers to the nervous system's ability to re-organise its structure and function in response to stimuli (Kleim & Jones, 2008). Some of the principles of experience dependent neuroplasticity (Kleim & Jones, 2008; described page 25) have been highlighted in reference to the StepByStep approach, including: 1) 'use it or lose it' alongside evidence from Constraint Induced Aphasia Therapy (Pulvermüller et al, 2001), 2) 'salience matters' supports the personalisation of vocabulary items, 3) 'repetition matters' supports the repetitive nature of the exercises and 4) 'intensity matters' (Palmer & Mortley, 2011). Reference to the importance of 'intensity' has not been made in more recent publications (Palmer et al, 2019), as the recommended and actual intensity of therapy sessions is less than interventions defined as 'intensive' within the Cochrane review of aphasia therapy (Brady, 2016). However, the idea of providing 'more' therapy than would be available through traditional face-to-face methods of delivery still underpins the use of the StepByStep approach to aphasia computer therapy (Palmer et al, 2019).

Other theories that have been incorporated into the design of the StepByStep approach include the principle of errorless learning by starting with tasks that the PWA can achieve more easily (Fillingham, 2006). The tailoring of the type and difficulty of therapy exercises is supported by evidence of the effectiveness of Model Oriented Aphasia Therapy, which tailors exercises based on the symptoms of the patient (Barthel et al, 2008). The StepByStep approach was designed to be used in the long-term after stroke and the timing of delivery has been influenced by evidence demonstrating the possibility for improvement of long-standing aphasia (Raymer et al, 2008). Feedback has recently been highlighted as a principle underpinning the intervention (Palmer et al, 2019) as the latest version of the software includes a voice recognition function to support this principle. The importance of feedback is a key principle of learning theory (Thurlings et al, 2013).

Development of the StepByStep approach

The StepByStep© software was developed in response to an evaluation of an earlier piece of software called INTACT. The INTACT software was used alongside a remote working tool in a feasibility study with seven participants, which found that whilst it enabled more opportunity for practice, the software was not fit for purpose (Mortley et al, 2003). The StepByStep software was developed in accordance with suggestions from the earlier feasibility study (improved data transfer and visualisation of results) and evaluated in a case series study with seven participants using an ABA crossover design (Mortley et al, 2004). The intervention period was associated with improved picture naming, which was maintained six weeks post-intervention. The authors claimed in-depth interview data demonstrated improvement in functional communication for four participants, but this appears to have been a subjective judgement. Interview data also demonstrated the acceptability of remotely delivered aphasia computer therapy (Wade et al, 2003). The team behind the StepByStep software (Steps Consulting Ltd.) have utilised their expertise as a SLT and systems analyst to continue to develop the, now commercially available, software. It has gone through many iterations with regular updates in response to changes in hardware, errors and feedback from PWA and clinicians using the software. The StepByStep software has more recently been re-conceptualised as one component of the StepByStep approach, which acknowledges the role played by SLTs, volunteers and informal carers in the tailoring and personalisation of the therapy exercises and the on-going monitoring and support required for the PWA to engage in regular self-managed practice (Palmer & Mortley, 2011).

A pilot, single-blinded RCT investigated the feasibility of establishing the clinical and cost-effectiveness of the StepByStep approach to aphasia computer therapy versus usual stimulation (CACTUS; Palmer et al, 2012). A volunteer supported and monitored the patients' self-managed practice whilst liaising with the SLT to seek advice and support. Remote monitoring by an SLT, although technically possible with the software, was not used during the trial due to lack of readiness of NHS services and limited access to the internet for much of the population of PWA requiring treatment. The intervention period lasted five months. Assessments were conducted blind to intervention allocation at baseline, five and eight months. As a pilot trial, the primary outcome measures related to the feasibility of conducting a fully powered RCT, but clinical outcome measures included naming assessments of trained and untrained words, as well as measures of cost-effectiveness. The pilot study established that it would be feasible to conduct a fully powered study. Thirty-four participants were recruited (17 per group). Participants in the computer therapy group carried out an average of 25 hours practice, but there were large variations between the number of practice sessions per week (mean varied from 1-7) and the average length of

practice sessions (mean varied from 7-46 minutes) (Palmer et al, 2013). SLT input averaged 4 hours 43 minutes and volunteer input averaged four hours. However, four intervention group participants did not have access to a volunteer and three of those participants practised less than recommended. The intervention improved naming of trained words (Palmer et al, 2012) and the incremental cost effectiveness ratio (ICER) was £3,285 per additional Quality Adjusted Life Year (QALY) gained, suggesting that the intervention was likely to be cost-effective based on an ICER threshold of £20,000 per additional QALY gained (Latimer et al, 2013). Qualitative interviews conducted with the PWA receiving the intervention, and their carers, described the independence, flexibility and opportunity for repetition provided by the therapy as benefits of the intervention and participants perceived motivation to practise was increased by the personalisation of vocabulary (Palmer et al, 2013).

StepByStep approach in the Big CACTUS trial

The key differences between the intervention trialled in the CACTUS pilot study and the fully powered Big CACTUS study was the use of a new version of the StepByStep software (version 5.0, rather than version 4.5) which incorporates voice recognition technology to provide feedback to the PWA on whether the correct word has been produced, the intervention period lasting 6 months, rather than 5 months and support being provided by therapy assistants as well as volunteers to reflect the range of personnel used to provide support in NHS SLT services (Palmer et al, 2012; Palmer et al, 2019). The StepByStep approach to aphasia computer therapy trialled in the Big CACTUS study is described in the therapy manual written by the chief investigator of the Big CACTUS study based on her clinical experience of delivering the intervention (Palmer, 2015; see appendix A). The intervention was reported using the TIDieR template by the Big CACTUS trial team (figure 1.3).

Why?	To provide increased amounts of SLT long-term for people with word finding difficulties post-stroke. The aim was to adhere to key principles of experience-dependent neuroplasticity (salience, repetition, feedback).
What?	Word finding exercises were provided on a computer (PC, laptop, or tablet) owned by the participant or loaned by the NHS trust. The StepByStep aphasia software was used as it can be tailored to the individual's needs, allows presentation of personally relevant words (e.g. grandchildren's names), encourages repetitive practice, and provides feedback about whether the words used are correct.
Who provided?	Speech and language therapists provided the software. Volunteers or therapy assistants provided encouragement and support to practise computer exercises, practised using new words in functional contexts, and fed back on progress to the therapist.
How?	Practice of the word finding exercises on the computer was self-managed by participants.
Where?	Participants' own homes.
When and how much?	20–30 min practice daily was recommended over a 6-month period (based on feasibility shown in the pilot study). Volunteers or therapists assistants were asked to visit for at least 1 h once a month.
Tailoring	Therapists chose therapy exercises based on the results of baseline language assessments. They also worked with the participants and their families to identify 100 words of personal relevance for therapy practice.
Modifications	Therapists were advised that they could set the 100 words up in stages rather than all at once.
How well?	Therapists were provided with 1-day training on the intervention. An intervention manual was provided. Fidelity to practice adherence and quality of therapy delivery by the therapists and volunteers or therapy assistants was assessed (see appendix p 106).

Figure 1.3. TIDieR template of trial intervention (Palmer et al, 2019; licenced under CC BY 4.0; modified to include only information about the intervention group)

The StepByStep computer software (version 5.0) went through several minor upgrades to fix glitches in the time it was used in the trial. A library of images is included in the software but any image can be added so PWA can learn words of personal relevance (i.e. salience). Below are a series of print screens showing the various exercises (also known as steps) included in the therapy software. Most of the exercises have different cue or prompt buttons (e.g. first letter, first sound, whole word, voice recognition) which can be selected or

deselected based on the individual's specific impairment (i.e. tailoring). Additional copies of all of the exercises can be made and adapted to allow for graded presentation of prompts to enable errorless learning. The five exercise types are described below based on information from the therapy manual (Palmer, 2015). Without any adaptation seven exercises are pre-programmed. The confrontation naming exercise and naming from grid exercises are duplicated (more information below).

Picture recognition: this exercise is designed for familiarisation with the items using a simple matching task (see figure 1.4).



Figure 1.4. Screenshot of picture recognition exercise in the StepByStep© Software (Steps Consulting Ltd)

Confrontation naming: this exercise presents the PWA with an image of the target word to name with cues at the bottom of the screen. The PWA should be encouraged to click on the cues from left to right. This step is pre-programmed to be presented twice with the first presentation as below and the second presentation showing the voice recognition prompt. The voice recognition provides feedback to the PWA about whether the correct word has been retrieved (see figure 1.5).

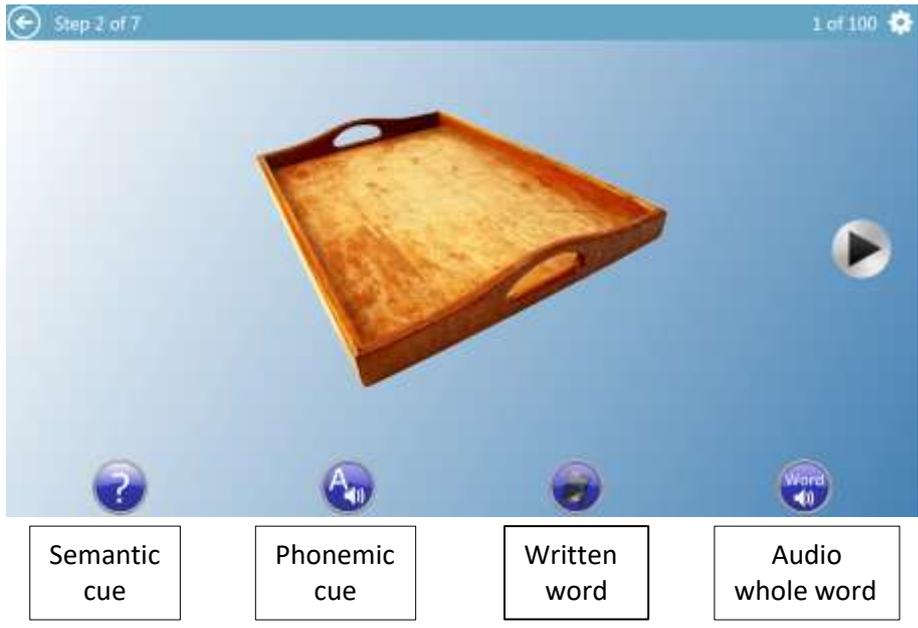


Figure 1.5. Screenshot of confrontation naming exercise in the StepByStep© Software (Steps Consulting Ltd)

Using writing to cue naming: This exercise shows an anagram for the PWA to unscramble (can be altered to spell whole word or select first letter) in order to prompt retrieval of the word. The PWA can either type a response or once they know what the word is they can press the voice recognition button, record the spoken word and receive feedback (see figure 1.6).

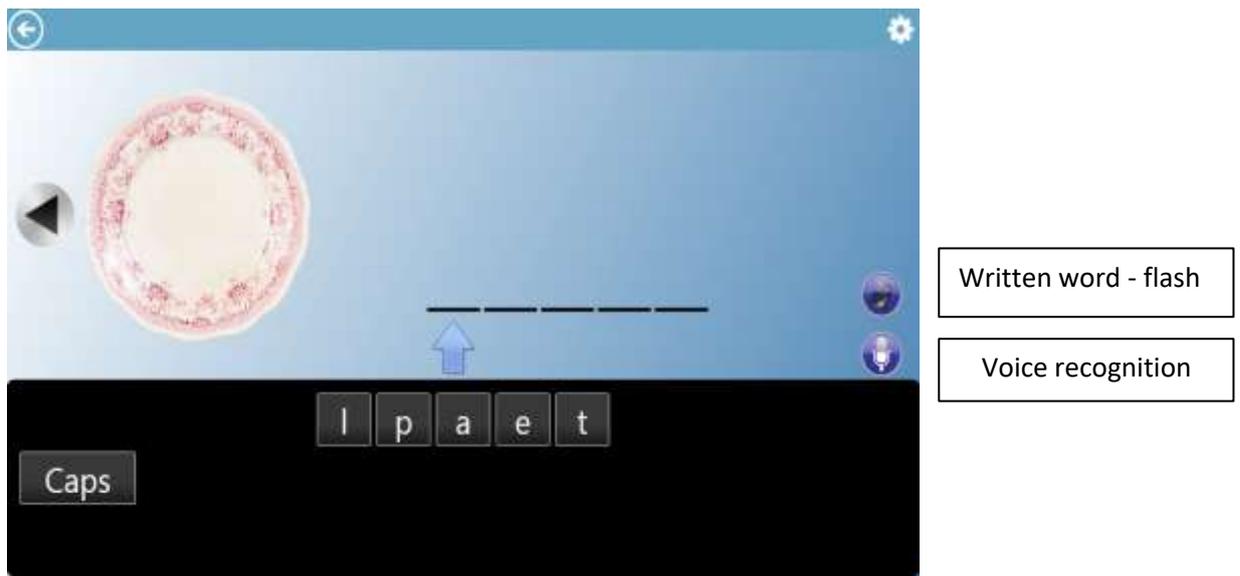


Figure 1.6. Screenshot of using writing to cue naming exercise in the StepByStep© Software (Steps Consulting Ltd)

Naming from a grid: The initial naming from a grid exercise requires the PWA to name the items without cues. The PWA should be instructed to press the voice recognition button to record the spoken word and receive feedback. The second type of naming from a grid exercise requires the PWA to name from memory the items presented in the previous grid step. If they press the voice recognition button and say a correct word from memory the picture is revealed (see figure 1.7). Whilst these exercises target different aspects of language processing (confrontation naming vs naming from memory), they are presented together because the system records time spent on them collectively (this will be of relevance in chapters four and six).

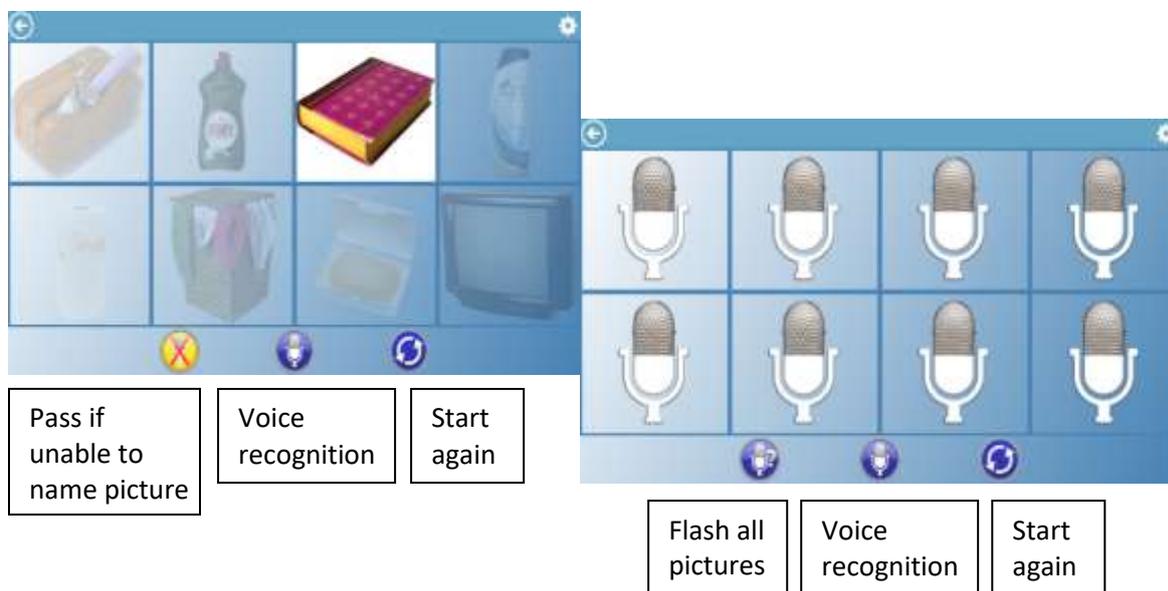


Figure 1.7. Screenshot of using naming from a grid exercise in the StepByStep© Software (Steps Consulting Ltd)

Using words in functional sentences: This exercise asks a question and requires the PWA to answer the question by using the target word in a sentence (see figure 1.8).



Figure 1.8. Screenshot of using words in functional sentences exercise in the StepByStep© Software (Steps Consulting Ltd)

Big CACTUS trial design

Big CACTUS was a pragmatic, superiority, single blind, parallel group, individually randomised controlled adjunct trial that evaluated the clinical and cost-effectiveness of the StepByStep approach to aphasia computer therapy in the long-term post-stroke (Palmer et al, 2019). See appendix B for the trial protocol. The structure of the trial is shown in figure 1.9. Computer therapy (daily computer based therapy tailored by an SLT and supported by a SLT assistant/volunteer for six months plus usual care) was compared to usual care and activity/attention control (daily completion of paper based puzzles and regular phone calls from the research team plus usual care). The study took place in 21 sites across the UK. Outcome measures were performed by a blinded research SLT at baseline, 6, 9 and 12 months and included co-primary outcomes to measure participants' word-finding ability (a naming test of treated words of personal relevance) and functional communication ability (videoed conversation rated using the activity scale of the Therapy Outcome Measure scale; TOMS; Enderby et al, 2013). Other secondary outcomes included use of specific treated words in conversation, generalisation of word-finding skills to untreated words (measured using the naming objects sub-test of the Comprehensive Aphasia Test (CAT; Swinburn, 2004), participation and quality of life (measured using the Communication Outcomes after Stroke Scale; COAST; Long et al, 2008) as well as health economics and carer measures (Palmer et al, 2019).

Participants were eligible if they were aged 18 or over with a diagnosis of aphasia caused by a stroke at least four months prior to randomisation. Participants had to score between 5 and 43/48 on the Naming Objects sub-test of the CAT (Swinburn, 2004), perform a simple matching task in StepByStep with at least 50% accuracy to confirm their ability to use the software, and repeat at least 50% of words in a simple word repetition task in StepByStep to rule out significant dyspraxia for which a different intervention would be more appropriate. Participants were excluded from the study if they had another pre-morbid speech and language disorder, required treatment in a language other than English (as the software was in English) or were currently using the StepByStep software or another therapy program aimed at word retrieval. 278 participants were recruited to the trial. Computer therapy significantly improved word-finding ($p < 0.0001$) 16% more than usual care and 14% more than attention/activity control), but did not generalise to improvement of functional communication on the TOMs or quality of life on the COAST significantly more than usual care or attention/activity control. Cost-effectiveness was uncertain, but computer therapy appeared to be more cost-effective for those with mild/moderate word-finding impairment (Palmer et al, 2019).

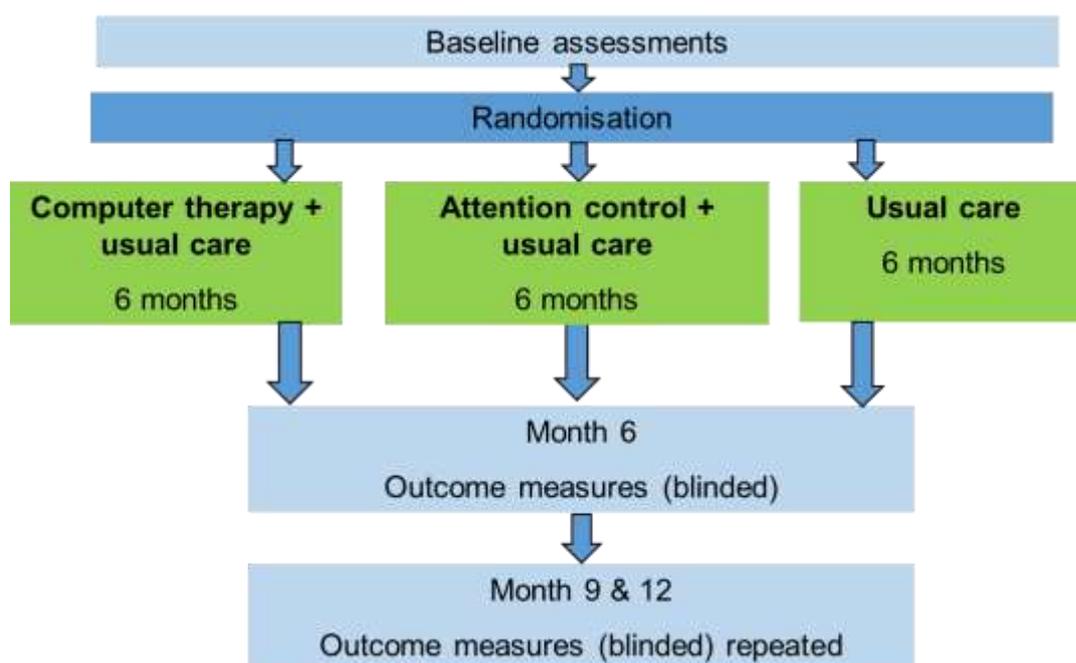


Figure 1.9. Big CACTUS trial structure

When the trial was initially designed and funded no fidelity evaluation was planned. The author was awarded a Stroke Association Postgraduate Fellowship to carry out a study of intervention fidelity to the StepByStep approach to aphasia computer therapy in the Big CACTUS trial.

1.6 AIMS AND OBJECTIVES OF THE PHD

The overall aim of this thesis is to evaluate the intervention fidelity of aphasia computer therapy delivered within the Big CACTUS trial. This aim will be addressed by meeting the following objectives:

1. Methods used to evaluate intervention fidelity in the field of stroke rehabilitation will be reviewed (study one; chapter two)
2. Key components of the StepByStep© approach to aphasia computer therapy will be described and methods of measurement explored (study two; chapter three).
3. Intervention fidelity to the StepByStep© approach to aphasia computer therapy in the Big CACTUS trial will be evaluated (study three; chapter four).
4. Factors associated with adherence to aphasia computer therapy practice will be explored (study four; chapter five).
5. Components of the StepByStep approach to aphasia therapy that are 'essential' to produce the desired outcome will be identified (study five; chapter six).

1.7 METHODOLOGICAL APPROACH

This section describes the mixed methods research design of the thesis as a whole (the methods for each individual study are described in the corresponding chapter), including the author's epistemological position, how the evaluation of fidelity was carried out alongside a randomised controlled trial and the inclusion of patient, carer and public involvement.

Mixed methods research design

Mixed methods research refers to a study, or series of related studies, using both qualitative and quantitative data collection and analysis methods to address the same, or associated, research questions (Johnson & Onwuegbuzie, 2004). A mixed methods approach was chosen because it best addressed the research questions. The research questions for each study are shown in figure 1.10. Mixed methods researchers highlight the importance of articulating how different methods are integrated or complement one another (O'Cathain et al, 2010). To illustrate how this will be achieved within this thesis the methods used to address each question are presented in figure 1.11, which maps onto the figure displaying the research questions. Figure 1.11 will be shown at the start of each chapter, with the relevant chapter highlighted, to guide the reader through the thesis.

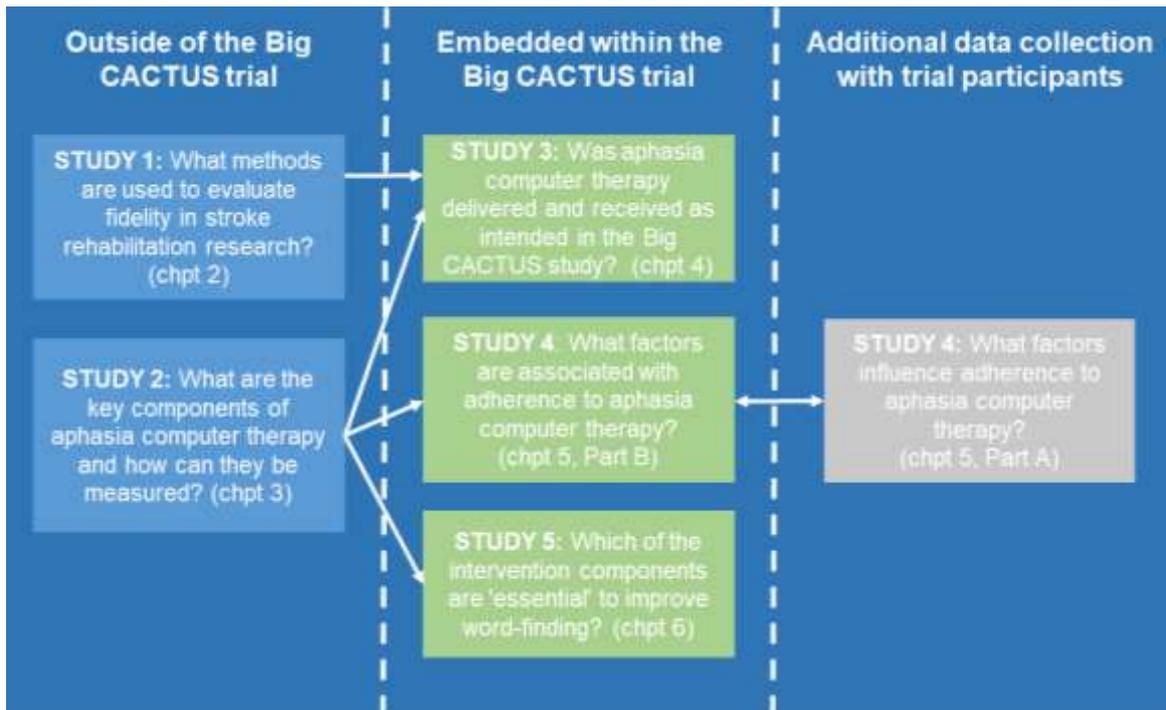


Figure 1.10. Thesis structure detailing the research question addressed in each study

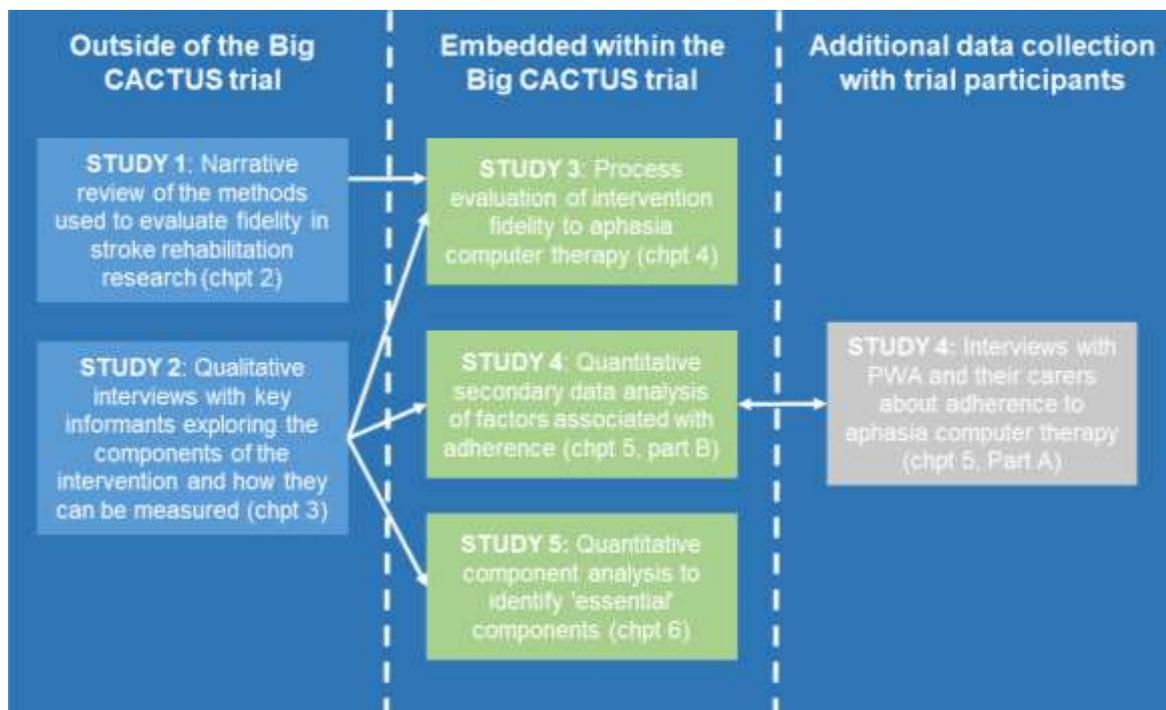


Figure 1.11. Thesis structure detailing the methods used in each study

Creswell's (2003) mixed methods typology informed the description of how the different studies influenced one another. A *sequential exploratory* design was adopted, whereby qualitative exploration of the key components in study two informed the quantitative evaluation and exploration of these components in studies three, four and five. This is illustrated by the direction of the arrows stemming from study two shown in figures 1.10 and 1.11. The findings from the qualitative interviews in study two directly informed: 1) the data collected in the process evaluation of fidelity in study three; 2) the intervention variables available for inclusion in the secondary analysis in study four; and 3) the components (i.e. variables) included in the component analysis in study five. In study four, a *concurrent triangulation* design (Creswell, 2003) was adopted collecting qualitative data (part A) and quantitative data (part B) about the same topic with the potential to validate the results across the two methods by integrating the findings (part C). This is illustrated by the bi-directional arrow shown between part A and part B in figures 1.10 and 1.11.

The Big CACTUS trial quantitatively investigated the effectiveness of aphasia computer therapy, whereas this thesis aims to explore the fidelity of the intervention through a series of qualitative and quantitative studies guided by the CFIF (Carroll et al, 2007):

- Study one, narrative review of the methods used to evaluate fidelity in stroke rehabilitation studies used the CFIF to guide data extraction.
- Study two, definition of the key components of the intervention through qualitative interviews with key informants as there was insufficient existing evidence about the StepByStep approach to enable a component analysis to be carried out.
- Study three, assessment of different elements of fidelity for the key components of the intervention in a process evaluation carried out alongside the Big CACTUS trial.
- Study four, exploration of the factors associated with adherence explored in more detail.
- Study five, investigation of the relationship between the 'essential' components and the outcome, improved word-finding.¹

Figure 1.12 illustrates how studies two to five map on to the CFIF.

¹ Justification for the methods described will be provided in each of the relevant chapters.

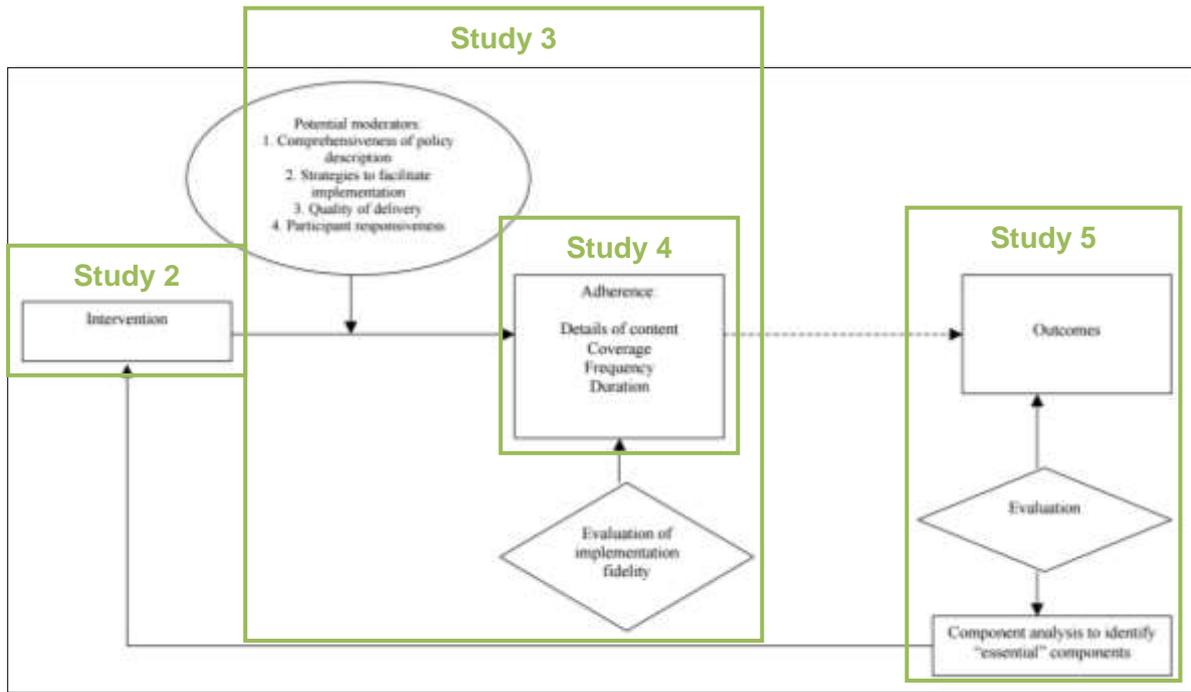


Figure 1.12. Conceptual framework for implementation fidelity (Carroll et al, 2007; licenced under CC BY 4.0; reproduced with additional annotation)

Epistemological position

A positivist epistemological position is assumed to underpin quantitative research, such as the Big CACTUS trial. Whereas, qualitative researchers more often state their epistemological position (Tong et al, 2007), believing it to enhance the credibility of their research (Caelli et al, 2003). The author adopted a philosophical approach of subtle realism, therefore positioning herself centrally between positivism and constructivism. Subtle realists recognise the existence of an underlying reality, which can be investigated, but acknowledge that subjective perception will always influence research, meaning research data are socially constructed (Mays & Pope, 2000; Hammersley, 1992). Subtle realists support the notion that the research method chosen should be the one that can best address the research question (Duncan & Nicol, 2004). The subtle realist approach is consistent with a mixed methods design (O’Cathain et al, 2010).

Carrying out research alongside a randomised controlled trial

A recent systematic review established that the majority of qualitative research conducted alongside RCTs was employed to investigate the intervention being trialled (O’Cathain et al, 2013), as was the case in this study. This thesis only includes data from the intervention arm of the Big CACTUS trial because the aim of the research was to explore fidelity to the intervention.

Study one (narrative review of fidelity evaluation methods) and study two (qualitative exploration of intervention components) were conducted by the author outside of the Big CACTUS trial in order to inform the design of the fidelity evaluation (see figure 1.11). The quantitative components of studies three (process evaluation of fidelity), four (secondary analysis of factors associated with adherence) and five (component analysis) were embedded in the trial. Some of the quantitative data informing studies three, four and five was collected as part of the trial, but the author identified the need for some additional quantitative data. The author designed methods to collect this additional data and carried out data collection during the trial, including: the therapy planning form, Working Alliance Inventory, lead therapist quiz and visual analogue scales (see chapter four for more detail). All qualitative data collection was designed and conducted by the author. Furthermore, all of the analysis described in this thesis (both quantitative and qualitative) was carried out by the author. Prior to, and alongside working on their thesis, the author worked on the Big CACTUS trial as a research associate setting-up study sites, providing training to SLTs working on the trial and monitoring study activities. The author was conscious of not relaying any findings from the fidelity evaluation to those providing the therapy in order to minimise the impact of the fidelity evaluation and avoid any unplanned modifications of the trial intervention (Cooper et al, 2014).

Patient, carer and public involvement

Public involvement has the potential to improve the quality, credibility and relevance of the research design, process and findings (Sutton, 2008). The benefits of involvement from the stroke survivor and carer perspective include keeping researchers grounded, being able to ask lay questions and playing a role in directing the research agenda (Harrison & Palmer, 2015). The Big CACTUS trial Patient and Carer Advisory Group, established during the development of the pilot CACTUS trial, continued to meet regularly throughout the trial. The Advisory Group have been involved in facilitating the recruitment and inclusion of PWA in the

Big CACTUS trial, ensuring trial and intervention materials and processes were accessible to PWA and disseminating the results.

The author worked with the Big CACTUS Patient and Carer Advisory Group to ensure information sheets and data collection tools for additional data collected for the fidelity evaluation were accessible to PWA. This included the scales to measure motivation, ease of use and personalisation used in the process evaluation in study three (chapter four), as well as the development of the interview schedule and supporting scales and images used in PWA and carer interviews in study four (chapter five).

1.8 SUMMARY

This chapter has set the context for this thesis by describing the concept of fidelity, how fidelity has been evaluated in aphasia studies and the development of the StepByStep approach to aphasia computer therapy, as well as its evaluation within the Big CACTUS trial. The aims, objectives, structure and methodology of the fidelity study as a whole have been described. Each of the following five chapters presenting findings will include a discussion section (with strengths and limitations and future research). Consequently, the final discussion chapter will cover broad themes emerging from the research as a whole alongside the clinical implications and suggestions for intervention refinement.

Chapter Two: A Narrative Review of the Methods used to Evaluate Intervention Fidelity in Stroke Rehabilitation Studies

The aim of this chapter was to review the methods used in existing fidelity evaluations in order to inform the choice of methods used to evaluate fidelity to the StepByStep computer therapy intervention in the Big CACTUS trial. An existing review of fidelity evaluation in aphasia treatment studies identified 21 studies that described some aspect of fidelity evaluation or enhancement (Hinckley & Douglas 2013). Only two evaluation methods were used (video and direct observation) and the average number of participants in each study was three. In order to explore a wider variety of methods, this review focused on the methods used to evaluate intervention fidelity in the wider field of stroke rehabilitation. The search was initially carried out in 2016 and updated in 2019. The update follows presentation of the initial results.

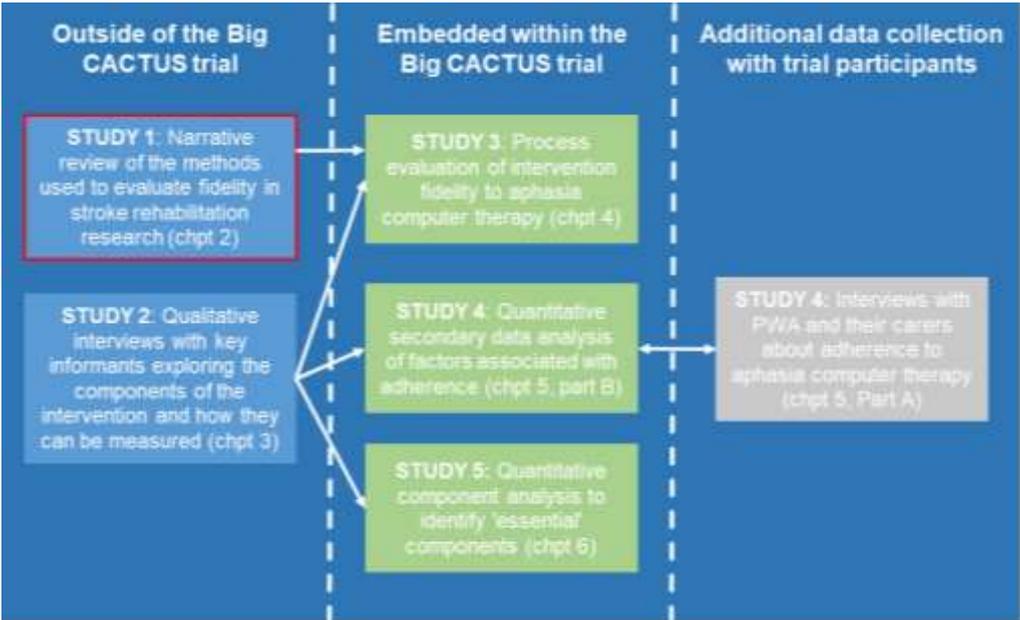


Figure 2.1. PhD structure with red border indicating the current chapter

2.1 INTRODUCTION

Rehabilitation interventions are notoriously complex (Hoffmann et al, 2014); typically comprising multiple components that require the active involvement of the patient and one or more therapists to achieve the desired outcome (Poltawski et al, 2014). As described in the background chapter, the fidelity of an intervention refers to whether an intervention is delivered as intended (Bellg et al, 2004). Understanding the degree of fidelity with which an intervention has been delivered is crucial for the accurate interpretation of treatment effects (Perepletchikova & Kazdin, 2005). However, the more complex an intervention, the harder it is to determine whether it is being delivered as intended, because it is necessary to monitor multiple components of the intervention, which is both time consuming and costly (Schoenwald et al, 2011). This creates a challenge for those aiming to evaluate the fidelity of rehabilitation interventions.

A review of reviews about fidelity identified four main methods of observing intervention delivery and receipt including direct observation, audio observation, video observation and self-report methods (Gearing et al, 2011). The many and varied approaches taken to evaluating fidelity are thought to be the result of inconsistencies in definition, understanding and application of fidelity (Gearing et al, 2011). Schoenwald and colleagues (2011) proposed a series of steps that describe the process of measuring fidelity: 1) identify relevant intervention components; 2) determine who will rate the components; 3) obtain ratings; and 4) devise a summary score based on the ratings. However, they also acknowledged that each step involves multiple choices and decisions and established that researchers' choice of measurement method was often dependent on the availability of resources; direct observation of the intervention is perceived to be most effective, but a self-reported measure of fidelity is usually more efficient. Mowbray et al (2003) caution the use of composite fidelity scores, suggesting that evaluators need to examine the structure of fidelity measures and consider presenting sub-scores for the different components. Furthermore, Salyers et al (2003) advises against direct comparison of fidelity scores across interventions because a number of interventions could all receive the same fidelity score, but be very different in their operations.

It is recognised that there will never be a one size fits all method to evaluate fidelity because evaluations need to be tailored to the intervention. Additionally, in the field of stroke rehabilitation the interventions will be targeting different impairments and activities as the consequences of stroke are multifaceted including motor, cognitive and language impairments. However, it is useful to understand the methods and approaches that other researchers have applied in similar contexts when designing a fidelity evaluation.

Aim and objectives

The aim of the review described in this chapter was to identify the methods used to evaluate intervention fidelity in the field of stroke rehabilitation. This aim was achieved by addressing the following objectives:

- identifying the methods of evaluation used to measure different elements of fidelity;
- interpretation of the extent to which the intervention was delivered as planned; and
- describing strategies used to enhance fidelity.

The purpose of conducting the review was to inform the choice of methods used to evaluate the StepByStep approach to aphasia computer therapy in the Big CACTUS trial.

2.2 METHOD

Search strategy

A systematic search strategy was applied to increase comprehensiveness. Search terms included “stroke”, “rehabilitation” and “fidelity”, as well as other synonyms and related concepts (see appendix C). Three databases were chosen to represent the diversity of disciplines involved in stroke rehabilitation: Medline (Ovid), PsychINFO (APA PsycNET) and CINAHL (EBSCO). An information specialist from a health services library was consulted in the development of the search strategy. The search was conducted on 7th February 2016.

Eligibility criteria and study selection

For inclusion, articles must have reported planned or completed primary research describing strategies to evaluate and/or improve intervention fidelity in a stroke population receiving a rehabilitation intervention. Whilst the participants could be staff (i.e. exploring aspects of delivery) or patients, studies were excluded if less than 50% of the individuals receiving the intervention were stroke survivors. Furthermore, the articles must have been written in the English language and published in a peer-reviewed journal within the last 20 years (1996-2016).

To increase the rigour of the selection process two reviewers (the author and supervisor, RP) independently selected articles for inclusion at the title and abstract selection stages. The full texts were read for inclusion by the author. Where there was uncertainty about inclusion a decision was made through discussion between the two reviewers.

Study quality

As the purpose of the review was to describe the methods used to enhance and evaluate intervention fidelity, the assessment of study quality, which is usually applied to reviews of intervention effectiveness to determine the degree of bias, was not required because the review did not aim to determine the effectiveness of the methods used.

Data extraction

The TIDieR checklist (Hoffmann et al, 2014) and the Conceptual Framework for Implementation Fidelity (CFIF; Carroll et al, 2007), which have been described in detail in chapter one, informed the process of data extraction. Two items on the TIDieR checklist relate to intervention fidelity. The first examines how the fidelity evaluation was planned “if intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them”. The second examines the degree of fidelity actually achieved “if intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned” (Hoffmann et al, 2014). The first was broken down into a series of discrete items and the second was applied directly to the studies identified (see below).

The lack of a clear definition of the term fidelity, and the elements of which it is comprised, means that different terminology is used to describe the same or similar features and processes in the literature. It was therefore necessary to translate the findings into a common rubric to create a meaningful summary of the elements of fidelity being evaluated (Popay et al, 2006). The CFIF was adopted as the common rubric in this instance as the CFIF has been selected as the framework to guide the fidelity evaluation detailed in this thesis (see chapter one, page 24, for more information; Carroll et al, 2007).

Informed by these two guiding documents, the following data was extracted and tabulated in excel: author name; year of publication; area of rehabilitation; short description of the intervention; study design; element of fidelity evaluated as defined by the CFIF (e.g. quality of delivery); method of fidelity evaluation (e.g. video observation); evaluation tool and scoring process; who carried out the evaluation, the theory or approach underpinning the evaluation and strategies to maintain or improve fidelity (e.g. training); and if fidelity was assessed, the extent to which the intervention was delivered as planned was described (e.g. second item of TIDieR relating to fidelity). Data extraction was conducted by the author.

Synthesis

A narrative synthesis was conducted, due to the qualitative nature of the data, using the key steps and tools recommended in guidance developed by Popay and colleagues (2006). The first step involved a preliminary synthesis of the findings, which started during the initial reading of the articles and influenced the choice of data extraction criteria and the selection of a common rubric to describe the data (e.g. CFIF; Carroll et al, 2007), which in turn enabled tabulation of the data (Popay et al, 2006). The second step required exploration of relationships in the data through consideration of the similarities, differences and patterns in the data using tools, such as conceptual frameworks (in this case the CFIF) and mind mapping (Rowley & Slack, 2004) and content analysis (Snilstveit et al, 2012). The final step recommended by Popay et al (2006) involves consideration of the robustness of the synthesis through critical reflection on the synthesis process. Aspects to reflect on include: the methodology of the synthesis, any assumptions made and any discrepancies or uncertainties in the findings (Busse et al, 2002). Reflections are described in the discussion of this chapter.

2.3 RESULTS

The search strategy returned a total of 127 articles. Once duplicates were removed, 109 articles remained for title review using the specified inclusion and exclusion criteria, which resulted in 57 articles being excluded. Abstract review was undertaken for the remaining 52 articles, at which stage 13 articles were excluded. Full text reading of 39 articles lead to a further 21 articles being rejected on the basis of not fulfilling the inclusion criteria, yielding 18 studies selected for inclusion in the review. For an illustration of this process see the PRISMA diagram (figure 2.2).

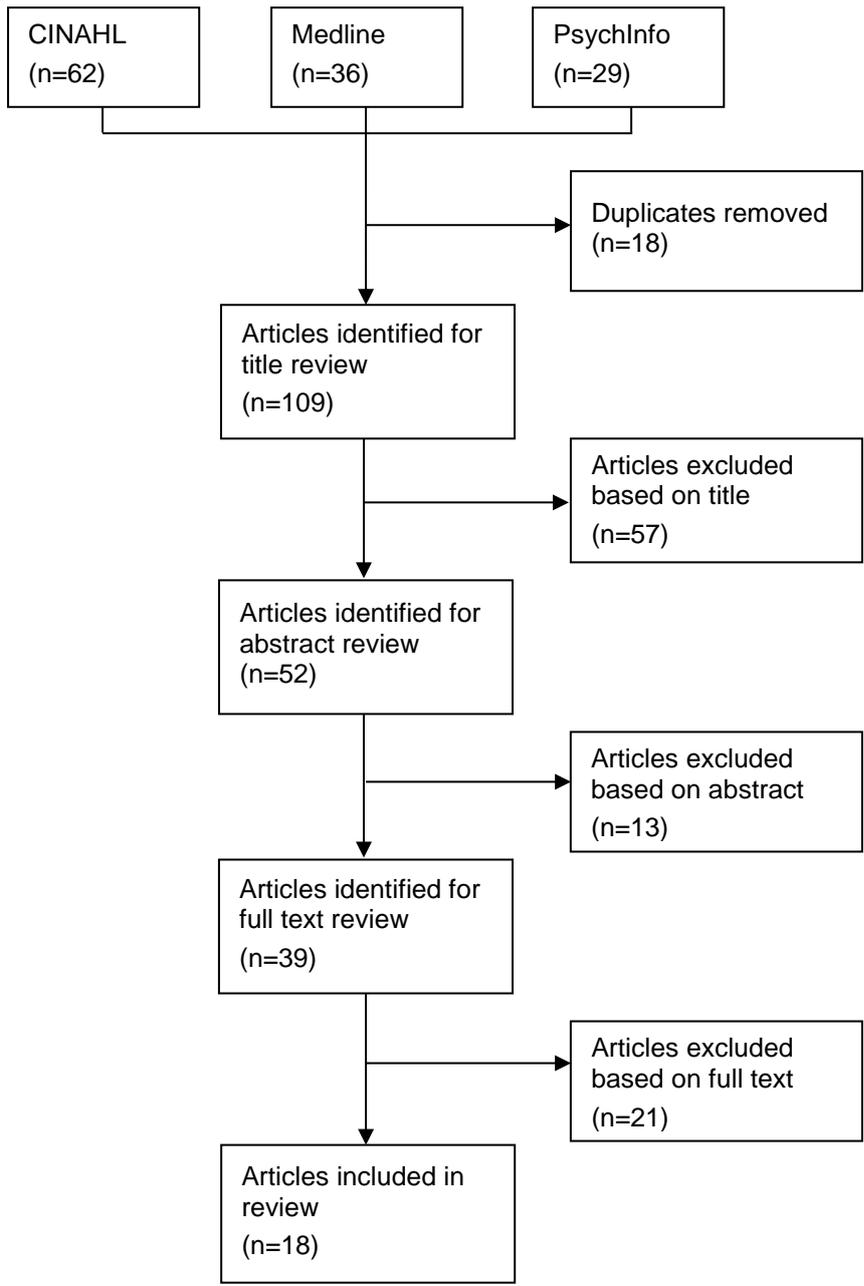


Figure 2.2. PRISMA diagram for article selection

For a full list of the articles included in the review see table 2.1 (articles numbers from the table are used for reference throughout the results section). The majority of studies targeted a single area for rehabilitation, whilst some targeted two or more (a maximum of two are listed). The area of rehabilitation targeted in the studies included movement (n=12), mood (n=4), communication (n=2), continence (n=1), and not specified (n=1). A wide range of interventions were included. In three instances the same interventions were being investigated in two different studies: Bridges stroke self-management program (1,2), strategy

training (11,12) and an exercise-based program (8,9). Four of the interventions were exercise based (2,8-10) and two had a technological component (7,13).

Article number	Author and year	Rehabilitation area	Short intervention description/name
1	Jones et al (2016)	Multiple including mood and movement	Bridges stroke self-management program
2	Jurkiewicz et al (2011)	Movement	Home-based exercise program
3	Mackenzie et al (2014)	Communication (dysarthria)	Non-speech oro-motor exercises
4	McKenna et al (2015)	Multiple including mood and movement	Bridges stroke self-management program
5	Morris et al (2009)	Movement (upper limb)	Constraint Induced Therapy
6	Östlund et al (2015)	Not specified	Family Health Conversations
7	Palmer et al (2015)	Communication (aphasia)	Computer software for language practice
8	Poltawski et al (2013)	Multiple including movement	Exercise-based program
9	Poltawski et al (2014)	Multiple including movement	Exercise-based program
10	Resnick et al (2011)	Multiple including movement	Exercise training intervention
11	Rosewilliam et al (2009)	Movement (upper limb)	Strategy training
12	Skidmore et al (2014)	Movement	Strategy training
13	Standen et al (2015)	Movement (upper limb)	Virtual reality system
14	Stock et al (2015)	Movement (upper limb)	Constraint induced therapy
15	Thomas et al (2011)	Continence	Systematic voiding program
16	Thomas et al (2013)	Mood	Behavioural therapy for stroke patients with aphasia
17	Vluggen et al (2012)	Multiple including movement	Transmural rehabilitation
18	Wheeler et al (2003)	Mood	Music therapy

Table 2.1. Rehabilitation area and intervention for studies identified

Despite the inclusion criteria starting in 1996, when some of the seminal fidelity work was conducted in the field of psychology, the earliest study identified was conducted in 2003. Whilst Wheeler et al (2003) do evaluate some of the constructs that are incorporated in a fidelity evaluation, (such as adherence to intervention frequency and content) they do not explicitly refer to the concept of fidelity. The earliest study to be included in the review to make explicit reference to fidelity was conducted in 2009 by Morris et al, thus indicating how recently the concept of fidelity has been applied in the field of stroke rehabilitation.

The type of study design was not an eligibility criteria for inclusion and consequently a wide variety of study designs were included in the review. The majority of studies (72%) were trials, including: randomised controlled trials (RCTs) (5,10,11,14,16), feasibility RCTs (1,3,4,13), RCT protocols (7,15,17), and a non-randomised two-group intervention pilot study (12). There were also before and after case-series (8,18), observational studies (2,6) and one article reported a series of experimental and non-experimental trial development studies (9). There did not appear to be a relationship between the type of study design used to investigate the effectiveness of rehabilitation interventions and the method of fidelity evaluation in these studies. However, there was a significant difference in the comprehensiveness of reporting depending upon whether the fidelity results were being presented as one part of a wider paper (1,3,4,7,11,12,15,17,18) or whether the papers focused on fidelity evaluation (2,5,6,9,10,16).

Methods used to evaluate the elements of fidelity

Adherence to content was the most commonly evaluated element of intervention fidelity reported in 16 of the 18 studies (see table 2.2). As such, it follows that it had the greatest variety of methods of evaluation, including self-report forms, direct observation, video observation, audio observation and electronic capture of content from intervention software (see table 2.3). Whilst adherence to content was most frequently assessed through self-report measures (n=11), it was also the component most frequently measured using observational methods (n=8). Adherence to the frequency of intervention delivery or receipt was evaluated in 13 studies and adherence to intervention duration in nine studies using the same modes of evaluation as adherence to content with the exception of audio observation, which was not used to evaluate duration. It is worth noting that the methods of evaluation for these three elements related to adherence are quantitative in nature although not necessarily objective (e.g. self-report measures), with the exception of one qualitative content analysis of audio observations (6). Two computer-based interventions were able to provide electronic records of the frequency and duration (13) and content (7) of therapy with automated data collection.

Article number	Author and year	Number and type of participants	Adherence				Moderators		
			Content	Frequency	Duration	Coverage	Participant responsiveness	Implementation strategies	Quality of delivery
1	Jones et al (2016)	78 patients	X				X		
2	Jurkiewicz et al (2011)	14 patients	X	X			X		
3	Mackenzie et al (2014)	39 patients	X	X	X	X	X		
4	McKenna et al (2015)	25 patients	X	X		X	X		
5	Morris et al (2009)	Staff – N/S ¹	X						
6	Östlund et al (2015)	6 staff	X						
7	Palmer et al (2015)	N/A ²	X	X	X				
8	Poltawski et al (2013)	6 patients	X	X	X	X	X		
9	Poltawski et al (2014)	N/S ¹	X	X	X		X	X	
10	Resnick et al (2011)	N/S ¹	X	X	X		X		
11	Rosewilliam et al (2009)	90 patients	X			X			
12	Skidmore et al (2014)	10 patients	X	X	X	X	X		X
13	Standen et al (2015)	17 patients		X	X	X	X		
14	Stock et al (2015)	24 patients	X	X	X	X			
15	Thomas et al (2011)	N/A ²	X	X				X	
16	Thomas et al (2013)	51 patients	X	X	X	X			X
17	Vluggen et al (2012)	N/A ²	X				X		
18	Wheeler et al (2003)	10 patients		X			X		
	Total		16	13	9	8	11	2	2

Table 2.2. Illustrating the elements of fidelity defined by the CFIF under evaluation in each of the articles included in the review

¹Not Specified – the number of participants was not specified in the article

²Not Applicable – protocols for planned research that had not yet recruited participants

The method for data collection relating to coverage was the most poorly reported aspect of adherence. Participant withdrawal was the most common means by which data relating to coverage was presented, but it was often not clear how, or by who, intervention or study withdrawal was recorded or at what point the participant withdrew (3,8,11,14). For example, they could have withdrawn post intervention receipt, but prior to the outcome measure being recorded (3), but this level of detail was frequently not provided. Studies with smaller sample sizes provided more detail about the time point at which participants withdrew and whether or not they had received the intervention prior to withdrawal (8,14). Sometimes the same form or treatment log used to record frequency and duration was used to record coverage. For example, if the forms record that all participants allocated to the intervention have received adequate frequency and duration then it was apparent that coverage was achieved (12).

Of the elements in the CFIF that were perceived to moderate adherence to the intervention, the most frequently evaluated element was participant responsiveness (n=9), which was evaluated as frequently as adherence to the duration of the intervention (see table 2.2). Participant responsiveness (participants willingness to engage with the intervention) was evaluated through self-report and qualitative interview methods only (see table 2.3). Strategies to facilitate implementation were evaluated through qualitative interviews in two studies (9,15). Whereas quality of delivery was evaluated quantitatively through video observation (12) and self-report methods (16).

Data collection tools

No standardised tool or form was used for data collection across more than one study. The type of data collection tool used differed between observational and self-report methods, with observational methods typically using checklists (1,5,10,12) and self-report methods more commonly using some form of treatment log for recording details of therapy sessions (4,10,11,15) or patient diaries (3,8,9). Whilst descriptions of self-report forms from the articles indicated similar data was collected, particularly regarding frequency and duration, they all used different terms to describe the forms used to collect the data, including: treatment log (4), questionnaire (17), recording sheet (15), training records (14), diary (7), protocol (11) or no name was specified (10).

Element of fidelity under evaluation defined using the CFIF (Carroll et al, 2007)	Number of studies evaluating each element	Method of evaluation used for each element	Number of studies using each method
Adherence to content	16	Self-report form	11
		Direct observation	4
		Video observation	3
		Audio observation	1
		Electronic record of content from intervention software	1
Adherence to frequency	13	Self-report form	10
		Direct observation	1
		Video observation	1
		Electronic record of frequency from intervention software	1
		Not specified	1
Adherence to duration	9	Self-report form	7
		Video observation	1
		Direct observation	1
		Electronic record of duration from intervention software	1
Adherence to coverage (i.e. whether those who should receive the treatment actually do)	8	Not specified	6
		Self-report form	2
Moderator: Participant responsiveness	11	Qualitative interviews	6
		Self-report form	6
Moderator: Strategies to facilitate implementation	2	Qualitative interviews	2
Moderator: Quality of delivery	2	Video observation	1
		Self-report form	1

Table 2.3. Element of fidelity evaluated defined using the CFIF and the corresponding mode of evaluation

Observational checklists typically resulted in a score that was perceived to indicate whether the intervention was delivered with fidelity (1,5,12), whereas self-report measures resulted in different types of data, such as a score from a questionnaire (18), the amount of actual therapy received compared to the intended amount (often reported as a percentage)(13), or more qualitatively reported results, such as questions about motivators and barriers to home-based workout sessions (2). Beyond checklists, other observational methods of collecting data included qualitative content analysis of audio recordings (6) and less

restrictive observation forms noting the nature and duration of activities and behaviour of the provider and client (8,9). No data collection tools, such as topic guides, were described in relation to the qualitative interviews although two studies did describe the topics addressed during the interviews (8,13). Several studies provided detail about the qualitative analysis process, including qualitative content analysis (6), thematic analysis (8) and framework analysis (15).

Observational checklists were generally completed by a member of the research team (1,3,5,10,12). Only one study made reference to whether those completing the observational checklists were independent (12), thus preventing the possibility for bias to be determined in the majority of studies. The key difference between self-report measures was whether they were completed by the intervention provider or the patient participant. Several of the rehabilitation interventions described in the included studies relied upon home based practice as well as therapy sessions with the intervention provider and in these instances the patients were often required to keep a diary or log of their independent practice (2,3,8,9).

The majority of studies included in the review did not specify a theory or framework underpinning the fidelity evaluation (n=15). The two sensitising theoretical frameworks used to guide the design of fidelity evaluations included the National Institutes of Health Behaviour Change Consortium fidelity framework (Bellg et al, 2004) (9,10) and the Conceptual Framework of Implementation Fidelity (Carroll et al, 2007) (6), which also influenced data extraction strategy for this review. Theoretical frameworks provided structure to guide data collection and reporting (9,10). Three studies framed their fidelity evaluation using a process evaluation methodology (1,5,17).

Strategies to enhance fidelity

Of the 18 studies included in the review, 16 described at least one strategy to enhance intervention fidelity, also referred to as *strategies to facilitate implementation* in the CFIF (Carroll et al, 2007). A total of 43 fidelity enhancing strategies were described, which have been grouped into 14 different types of strategies (see table 2.4). The most commonly used strategy to enhance intervention fidelity was the provision of training to participants prior to the provider starting to deliver the intervention (n=12). Only four of the articles that described the provision of training specified the length of the training provided, which ranged from two (4) to nine days (5). Most of the articles did not describe how the training was delivered, but one study described that a mixture of face-to-face and web-based training was used (15). The second most commonly used strategy that has the potential to improve the *quality of delivery* was the qualification of the provider, be that through professional qualification (12,13), accreditation (8,9) or being certified by a professional board (18). Four studies

described the use of examinations and observations completed after training to check the skills of the provider before they delivered the intervention (4,5,8,9), and in one case regular observation throughout the intervention period to check for drift in the skills of intervention providers (5). Other strategies to facilitate implementation used to improve the quality of delivery, a moderator variable in the CFIF, included: additional training at a later time-point (4), university course attendance (6), provision of supervision to the provider (16) or number of years of experience (8).

Strategies to enhance intervention fidelity	Number of studies
Providers attended initial training about the intervention	12
Qualification of provider	5
Requirement to pass written and/or observational examination	4
Additional training at a later time-point	1
University course attendance	1
Provision of supervision for the provider	1
Experience of provider	1
Provision of therapy manual or protocol	8
Key principles or components clearly defined for the intervention	4
Feedback loop from fidelity evaluation to improve aspects of delivery	1
Provision of a workbook to participants	1
Training for participant by provider for home-based independent practice	1
Supported implementation (facilitation to 'normalise' intervention)	1
Provider review of participant adherence and provision of encouragement	2

Table 2.4. Strategies to enhance intervention fidelity

Another proposed moderator of adherence from the CFIF is the *complexity of intervention description*. Two strategies to enhance fidelity that have the potential to influence this moderator are providing a therapy manual or protocol (n=8) or clearly specifying the key principles or components for the intervention and/or comparison condition (n=4). *Participant responsiveness* has also been targeted by strategies to enhance fidelity through training for the participant delivered by the provider to enable them to carry out home based independent practice using virtual reality, without which the participant would have been unable to engage with the therapy (13). Two studies described facilitated feedback processes to enhance fidelity. Thomas et al (2011) randomised participants to three groups: control, intervention and intervention plus supported implementation (15). The group receiving the supported implementation intervention benefitted from internal and external

facilitators focused on enabling and 'normalising' the intervention. Whereas Resnick et al (2011) provided feedback to providers following direct observation of adherence to content, duration and frequency (10). Those studies involving self-managed rehabilitation (i.e. practice conducted without the provider being present) employed two strategies: a workbook for participants which was perceived to standardise the content of the independent self-management activities (4) and provider review of participant adherence to independent practice and the provision of encouragement where necessary (3,7).

Findings from the interpretation of fidelity evaluations

The second item relating to fidelity on the TiDieR checklist recommends that "if intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned". Findings related to whether the intervention was delivered as planned were presented in 14 of the 18 studies included in this review. The articles not reporting findings were trial protocols (7,15,17) and an article that described fidelity evaluation methods across a series of experimental and non-experimental trial development studies (9).

How a decision was made regarding whether the intervention had been delivered with high or low fidelity was often unclear due to the majority of studies evaluating more than one element of fidelity using more than one data source. One study that only evaluated adherence to content through video observation stated that a 90% score would indicate good fidelity and found that the mean score across providers was 90%, which was interpreted as good fidelity, although some providers scored as low as 72% (5). Several studies using multiple data sources did not provide an explanation of how the different scores or results were combined to reach a conclusion about the extent to which the intervention had been delivered with fidelity (1,3,16). Four studies explicitly evaluating fidelity, described the results without providing an interpretation of whether high fidelity had been achieved (3,6,8,16). Others reported that fidelity was acceptable (12) or had been confirmed (1), verified (3) or supported (15). Only two studies described the interactions between different elements of fidelity. Both linked data relating to adherence to frequency and duration with information about participant responsiveness, specifically patients perceptions of barriers to adherence (2,13).

2.4 LITERATURE REVIEW UPDATE

The literature review was updated in 2019 in order to identify any advancements in the field since the original review in 2016.

Method for update

The original purpose of the review was to identify how others had evaluated fidelity in the field of stroke rehabilitation research in order to inform the author's own evaluation of fidelity. As the author's evaluation was completed prior to the review update, the update had a narrower scope to: 1) identify the number of additional studies published since the initial search, that describe fidelity evaluation in stroke rehabilitation research, 2) identify the intervention and area of rehabilitation of new studies, and 3) describe those articles only for whom fidelity evaluation was a primary focus. Detail of new approaches or thinking, in the field of fidelity evaluation, was thought to be most likely to be reported by articles whose primary focus was fidelity. It would have been preferable to have described all papers, but it was necessary to make the task manageable within a limited timeframe. Furthermore, the results were no longer needed to inform the design of the study, only to understand if and how the field has developed.

The original search strategy was re-run on 13th February 2019 using the same databases (see page 47). The same selection criteria were applied by one reviewer (the author). For those papers that focused on fidelity evaluation, data extraction followed the same process as the initial search.

Results for update

The search strategy returned a total of 213 articles across the three databases. At this stage, 13 articles were excluded as duplications. The title review stage included 200 articles and resulted in 113 articles being excluded. Abstract review was undertaken for the remaining 87 articles, at which point 28 articles were excluded. Full text reading of 59 articles led to a further 19 articles being rejected. A total of 40 articles met the inclusion criteria. This process is shown in the PRISMA diagram in figure 2.3.

Of the 40 papers identified in the 2019 search 18 were previously identified in the 2016 search and have therefore been described earlier in the chapter (see table 2.1). The 22 newly identified studies are listed in table 2.5 alongside the stroke rehabilitation area targeted and a brief description/name of the intervention. Similarly to the studies identified in the earlier search, most targeted a single area for rehabilitation, whilst some targeted two or more (a maximum of two are listed). The area of rehabilitation addressed in the articles

identified in the updated search covered the areas of movement (n=12), mood (n=6), communication (n=5), continence (n=1), and cognition (n=1). The studies were therefore carried out in broadly the same rehabilitation areas as those identified in the 2016 search. In both instances most of the studies targeted movement and the primary difference was the inclusion of a study exploring fidelity in the area of cognitive impairment, which was not included in the 2016 review. The interventions described were similarly diverse, ranging from psychotherapy to exercise to singing. The only noticeable difference was an increase in the number of studies that included a technological component (n=8), compared to the number identified in the initial search (n=2).

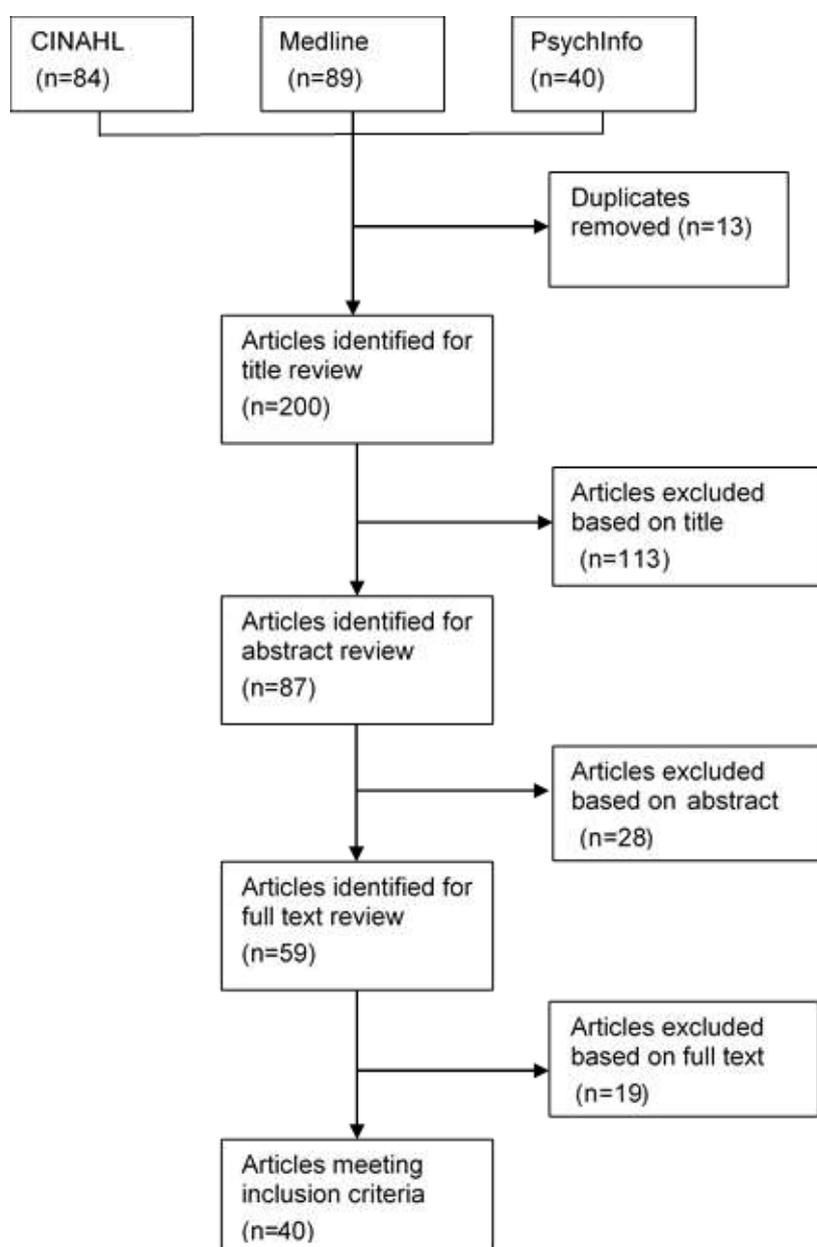


Figure 2.3. PRISMA diagram for the updated search

Author and year	Rehabilitation area	Short intervention description/name
Chesworth et al (2015)	Continence	Systematic voiding program
Chun et al (2018)	Mood (anxiety)	Individualised telemedicine based cognitive behavioural therapy
Cullen et al (2018)	Mood	Brief positive psychotherapy
Dean et al (2018)	Multiple including movement	Rehabilitation training exercise intervention
Emmerson et al (2017)	Movement (upper limb)	Home exercise programme on electronic tablet
Gunnes et al (2019)	Movement	Physical activity and exercise program
Holland et al (2018)	Mood	Motivational interviewing for PWA
Kara et al (2015)	Movement	Written and pictorial home exercise prescription
Kerr et al (2018)	Mood	Motivational interviewing
Kilbride et al (2018)	Movement (upper limb)	HOMe Based gaming exercise
Kirkevold et al (2018)	Mood	Dialogue-based psychosocial intervention
Lawrie et al (2018)	Multiple including movement	Smartwatch providing feedback of daily activity
Liu et al (2018)	Multiple including movement and communication	Family-led rehabilitation
Logan et al (2018)	Movement	Functional standing frame programme
Mitchell et al (2018)	Communication (dysarthria)	Online dysarthria speech therapy programme
Moore et al (2016)	Movement (upper limb)	Wristband Accelerometers to motivate arm Exercise
Patel et al (2018)	Mood	Motivational interviewing for PWA
Scianni et al (2012)	Movement	Strength training in addition to task-specific gait training
Stark et al (2018)	Movement	Community Participation Transition after Stroke
Tarrant et al (2018)	Multiple including communication (aphasia)	Group singing intervention for PWA
Wentink et al (2018)	Cognition	Computer-based cognitive rehabilitation
Woolf et al (2016)	Communication (aphasia)	Remotely delivered word-finding therapy

Table 2.5. Rehabilitation area and intervention for studies identified in the updated search

The majority of studies highlighted in the update (n=19) were published between 2016 and 2019, but the search also identified two studies from 2015 and one from 2012 that were not identified in the earlier search (see table 2.5). The year of publication for the studies identified across both searches are shown in figure 2.4. Since 2009 there has been an exponential growth in the number of studies evaluating fidelity. There was a marked increase in the number of papers published in 2018.

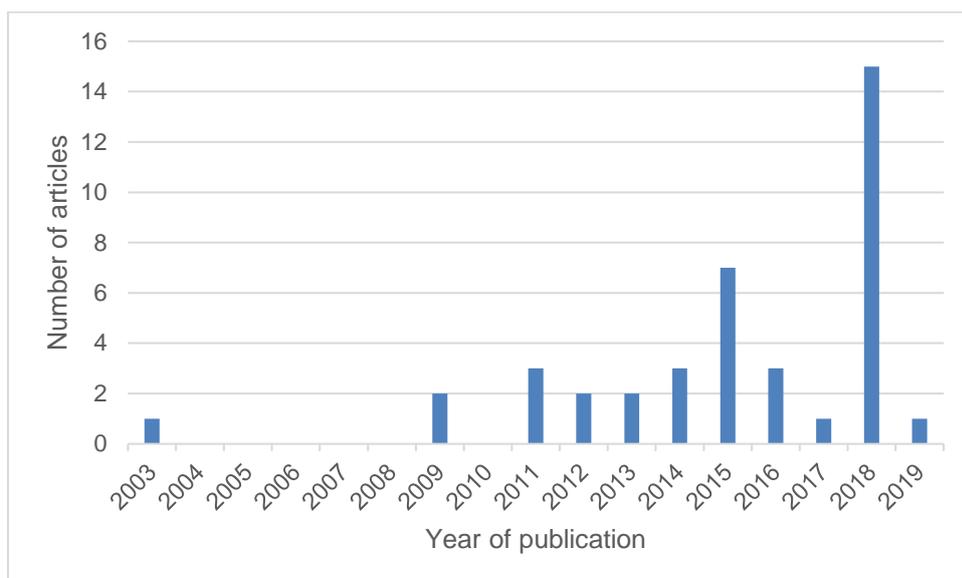


Figure 2.4. Number of studies found by year of publication. No studies were identified between 1996 and 2002 so these years are not shown on the graph.

Fidelity evaluation was the primary purpose of three of the 22 papers identified in the updated search. All three papers described different interventions for the rehabilitation of different areas: continence (Chesworth et al, 2015), mood (Holland et al, 2018) and movement (Liu et al, 2019). The paper written by Chesworth et al (2015) details the results of one of the protocols included in the initial search (Thomas et al, 2013). Two of the papers employed a process evaluation methodology, for which fidelity evaluation was one component, alongside a randomised controlled trial (Liu et al, 2019) and a cluster randomised feasibility trial (Chesworth et al, 2015). The other paper described a feasibility study evaluating fidelity to an intervention adapted for use with participants with communication impairment (Holland et al, 2018). Two of the papers cited the Behaviour Change Consortiums fidelity framework (Bellg et al, 2004) as a guiding influence, but there was no explanation for how it structured or guided their evaluation (Chesworth et al, 2015; Holland et al, 2018). A realist framework (Pawson & Tilley, 1997) and the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework (Gaglio et al, 2014) informed the process evaluation conducted alongside the ATTEND trial of family-led rehabilitation (Liu et al, 2019).

Across the three studies, all elements of fidelity identified as having been measured in the initial search were evaluated (as defined by the CFIF; Carroll et al, 2007). Adherence to content was the only item evaluated by all three studies. Two studies measured adherence to frequency (Chesworth et al, 2015; Holland et al, 2018) and adherence to duration (Holland

et al, 2018; Liu et al, 2019), but only one measured adherence to coverage (Holland et al, 2018). Of the moderators of adherence participant responsiveness was evaluated by two studies (Holland et al, 2018; Liu et al, 2019), implementation strategies by two studies (Chesworth et al; 2015; Holland et al, 2018) and only one measured quality of delivery (Holland et al, 2018). The study by Holland et al (2018) was the most comprehensive, evaluating all elements of fidelity.

All of the studies employed a different combination of methods. Two of the studies used self-report methods, including provider completion of clinical logs (Chesworth et al, 2015) and provider and participant completion of activity logs (Liu et al, 2019). Liu et al (2019) also employed qualitative interviews. Holland et al (2018) used video observation methods involving the application of a checklist called the Motivational Interviewing Skills Code (MISC). The level of detail provided about how the different instruments were scored varied significantly. Liu et al (2019) provided no detail about how the activity logs were scored. Chesworth et al (2015) provided information about the initial planned scoring method and how it had been adapted due to poor documentation. Both the planned and actual scoring methods used percentages to display the number of occasions the intervention was carried out on schedule and the percentage of times key components were included. Holland et al (2018) scored the intervention using the MISC checklist, which has a cut off score that indicates threshold delivery (i.e. satisfactory delivery) and one that indicates expert delivery. The MISC includes a global rating score of therapist and patient behaviours and the percentage of utterances consistent with the intervention.

All three studies reported the actual delivery of the intervention. Liu et al (2019) judged the intervention to have been delivered with high fidelity based on three out of four components having been implemented. It is not clear how implementation was determined as no scores were provided. As a large trial, including over 1000 participants, it would have been unlikely that every participant randomised to the intervention actually received each component, thus some sort of judgement must have been applied to determine whether the component was perceived to have been delivered with high fidelity, but this is not documented. Chesworth et al (2015) perceived fidelity to the intervention to have been relatively low, based on less than 40% of clinical logs having been properly documented and only 55% of those having provided the intervention within the specified time. Interestingly they also judged that fidelity to the delivery of two core components was high on the basis of them having been delivered 58-66% of the time (across two intervention groups). The percentage difference between the judgement for low and high fidelity was small and serves to highlight the lack of transparency behind the high/low judgement regarding fidelity. In contrast, the use of a checklist with a clear scoring system and small sample (n=3) allowed Holland et al (2018) to state in detail

how their fidelity judgement was made. Those participants for whom all of the fidelity ratings were at the threshold/expert level were classed as having higher fidelity than the participant with more variable MISC scores.

Strategies to enhance intervention fidelity fell into five categories. All three studies trained intervention providers and provided an intervention manual/protocol for the intervention providers. Additionally one study provided supervision for providers and required them to practise intervention delivery with ten volunteers prior to providing the therapy (Holland et al, 2018). The only study requiring participants to engage in independent rehabilitation activities in their own home also provided an intervention manual to the participants (Liu et al, 2018).

The notable differences between the updated and original search are 1) the increased number of studies detailing fidelity evaluation in recent years, and, 2) of the three papers described in more detail, all of them documented a sensitising theoretical framework compared to 17% of the original papers. Similarities between the two searches can be seen in the wide variety of different methods used to measure fidelity and the lack of clarity when translating a raw score into a judgement regarding the degree of fidelity.

2.5 DISCUSSION

A wide variety of methods have been used to evaluate fidelity in stroke rehabilitation interventions. Adherence to the content of the intervention was the most frequently evaluated element of fidelity, but there was no consensus around how this should be measured with a broad range of methods and data collection tools used across studies. Participant responsiveness was the moderator of adherence most frequently evaluated. Few studies considered how the different elements of fidelity interacted. The majority of studies incorporated at least one strategy to enhance intervention fidelity. The strategies were grouped into fourteen different types of strategy, with the most commonly implemented strategy being provision of training to the intervention provider.

In the field of stroke rehabilitation research, intervention content, frequency and duration were most commonly assessed through self-report methods. In contrast, a recent review of fidelity in diabetes self-management found that intervention content was mainly assessed through observation whilst dose (frequency x duration) was mainly assessed through self-report methods (Schinckus et al, 2014). The common use of self-report measures directly contrasts with findings from the field of aphasia, which exclusively employed observational methods (Hinckley & Douglas, 2013). Observational methods are perceived to be more effective than self-report methods, whereas self-report methods are perceived to be more

time and resource efficient (Schoenwald et al, 2011). Therefore, it might be that stroke rehabilitation researchers were opting for more efficient methods of evaluating fidelity at the expense of a more rigorous evaluation. Alternatively, it might be that the small sample size (average n=3) in the aphasia treatment studies (Hinckley & Douglas, 2013) reduces the time and resources required to carry out more rigorous observational methods.

Many of the studies in the review evaluated multiple intervention components (e.g. dose of physiotherapy and early supported discharge; Liu et al, 2019) and multiple elements of fidelity (e.g. adherence to content and participant responsiveness; Jones et al, 2016). The step between presenting, in many cases multiple, raw scores and overall judgement as to whether the intervention was delivered with fidelity lacked clarity and transparency or it was left to the reader to make their own judgement. Mowbray et al (2003) recommended the assessment of different sub-components of fidelity, but also highlighted the need to assemble the different scores to determine the overall degree of fidelity. However, even where this has been achieved the judgement of high/low fidelity still appears subjective (Chesworth et al, 2015). For the purpose of trials, it could be useful to publish in the protocol the score or series of scores that would allow high fidelity to be declared to increase transparency.

Despite having a broad time-span for the inclusion of studies, all articles explicitly referring to the concept of fidelity were written within the last decade (since 2009). This is indicative of a previous lack of awareness of the importance of evaluating intervention fidelity in stroke rehabilitation research. Literature reviews in other areas of health research have similarly found that there are a limited number of studies providing information about fidelity evaluation (e.g. Schinckus et al, 2014). The 2019 update to the review reported in this chapter highlighted an upward trend in reporting of fidelity evaluation in stroke rehabilitation research. It is possible that the increase has been influenced by the increased prominence of the TIDieR checklist (Hoffmann et al, 2014) and the more recent consensus-based core recommendations from the Stroke Recovery and Rehabilitation Roundtable (SRRR; Walker et al, 2017). The SRRR recommendations focus on intervention development, monitoring and reporting. The monitoring recommendations are most relevant to fidelity, including: 1) building a fidelity assessment into trial protocols; 2) describing the method for measuring fidelity that is trial and intervention specific and 3) routinely reporting the training of rehabilitation providers and how their competence was assessed (Walker et al, 2017).

The use of strategies to enhance fidelity demonstrates the complexity of the relationship within and between the moderators of adherence and adherence itself as described by the CFIF (Carroll et al, 2007). For example, provider training is a *strategy to facilitate*

implementation typically used to improve the *quality of delivery* in order to improve *adherence to content*. The strategies to enhance fidelity identified in the review were tailored to specific interventions. Participant responsiveness, for example, is particularly relevant to interventions where patients self-manage their own rehabilitation at home. Studies incorporating home based practice as part of the intervention used strategies such as providing a workbook or manual, monitoring adherence or providing encouragement (Jones et al, 2016; Liu et al, 2019; Mackenzie et al, 2014; Palmer et al, 2015). In some of the pragmatic trials it was apparent that the strategies to enhance intervention fidelity were built into the intervention itself and would be expected to be employed as part of the intervention if delivered in clinical practice (Jones et al, 2016; Palmer et al, 2015). However, other strategies such as incorporating a feedback loop from the fidelity evaluation conducted by the research team to improve aspects of delivery are unlikely to be implemented in clinical practice (Resnick et al, 2011). Further research to evaluate the effectiveness of the different implementation strategies could enable more targeted use.

Implications for the thesis

The studies included in the original review influenced the design of the process evaluation of the StepByStep approach to aphasia computer therapy in the Big CACTUS trial. The review identified that a wide variety of methods had been used to measure fidelity in stroke rehabilitation research. No one-size fits all fidelity measure exists, or is likely to be created, due to the diverse nature of the interventions being evaluated. Therefore, the measure needs to be tailored to the intervention. The StepByStep approach is a self-managed intervention carried out in the PWA's own home. Consequently, observational methods would have been very invasive and could have potentially altered participants' perception of the intervention. Prior to the commencement of this PhD, fidelity evaluations in aphasia research had all used observational methods (Hinckley & Douglas, 2013). This review demonstrated to the author that it was acceptable to use other methods in the wider field of stroke rehabilitation. As a result, the author has chosen a combination of self-report methods and electronic data capture. The lack of clarity, or an accepted precedent, regarding what is judged to be high fidelity, found in many of the studies, demonstrated to the author the importance of having a clear process for scoring the degree of fidelity that was standardised across intervention components and elements of fidelity (see chapter four). Whilst only a small number of studies employed a theoretical framework to guide the fidelity evaluation in the original review, they appeared to convey benefits in terms of structuring the evaluation and reporting of findings. This contributed to the author's decision to use the CFIF to guide the fidelity evaluation of the StepByStep approach. It has been suggested that use of a fidelity framework at the design stage may prompt researchers to consider which elements

of fidelity are most important to monitor during the trial (Walker et al, 2017) and help to identify mechanisms through which the intervention can achieve its desired effect (Gitlin, 2013).

Strengths and limitations

The review is novel as there have been no previous attempts to review the methods used to evaluate fidelity in stroke rehabilitation research. The elements of the CFIF provided a comprehensive framework from which to present and group the findings and enabled a meaningful summary to be produced (Carroll et al, 2007). The method of searching based on key words relating to fidelity could be regarded as a weakness. It is likely that searching through a specific journal (as carried out by Hinckley & Douglas, 2013) would have enabled the inclusion of more studies that measured an element of fidelity without explicitly using the term or related terms. However, the purpose was not to establish how many studies had evaluated elements of fidelity, but to review the methods used. The literature review update carried out in 2019 did not extract data from all of the studies identified due to time constraints. However, data was extracted from the three papers for whom fidelity evaluation was a primary focus.

The data extraction and synthesis process was conducted by only one person, whilst this can be an advantage in terms of consistency it is important to bear in mind that the findings were subject to only one interpretation. The synthesis process was complicated by the diversity of the findings. Since each study had evaluated fidelity using a different method and different terminology it was a time consuming process to translate the information into a 'common rubric' to allow the data to be categorised and grouped (Popay et al, 2006). Using the CFIF (Carroll et al, 2007) as the 'common rubric' was based on an assumption by the author that this framework was the most useful fidelity framework due to its consideration of the interactions between the different elements (see page 24). The use of content analysis has been criticised by some as it is considered a reductionist technique (Dixon-woods et al, 2005), however without grouping and counting the findings it would not have been possible to explore patterns in the data.

Conclusions

Rehabilitation interventions require a tailored approach to fidelity evaluation demonstrated through the wide variety of methods and tools specific to each intervention under investigation in this review. Therefore, the measures chosen to evaluate fidelity in the Big CACTUS trial were tailored to the StepByStep approach to aphasia computer therapy. The next chapter will explore the components of the intervention in more detail in order to achieve this. The review also identified a lack of clarity in how judgements are made regarding the degree of fidelity. Consequently, a transparent scoring system was applied to the fidelity evaluation described in chapter four in order to make an objective and transparent judgement about the degree of fidelity with which the intervention was delivered. Whilst few papers used theoretical frameworks in the original review, for those that did, they provided a beneficial structure for data collection and reporting, which supported the author's decision to use the CFIF as the sensitising framework for this thesis.

Chapter Three: StepByStep Approach to Aphasia Computer Therapy: Establishing the Key Components and Methods of Measurement

The previous chapter reviewed the literature to identify the fidelity evaluation methods used in stroke rehabilitation research. One of the key findings was that evaluation of fidelity to rehabilitation interventions should be tailored to the intervention. In order to tailor the design of the fidelity evaluation to the StepByStep approach the key components of the intervention were identified through qualitative interviews with StepByStep approach experts. Therefore, the aim of this chapter is to describe the key components, sub-components and theory behind the intervention and how the components interact, as well as identifying what should be measured in order to evaluate fidelity to the StepByStep approach and possible methods of measurement, thus informing the design of the fidelity evaluation described in the following chapter.

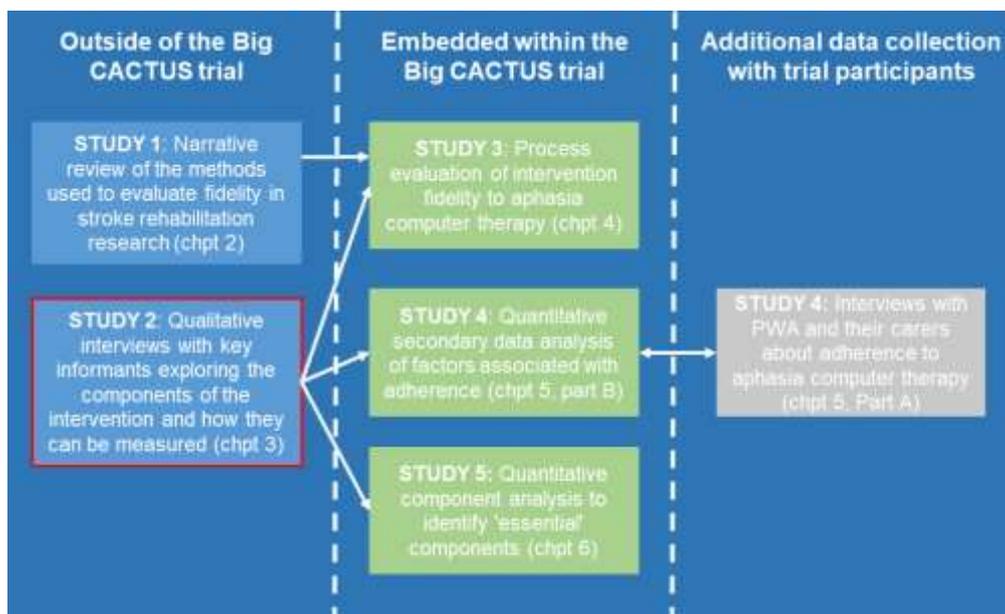


Figure 3.1. PhD structure with red border indicating current chapter

3.1 INTRODUCTION

Rehabilitation interventions are notoriously complex. This problem is compounded by the absence of established processes for their definition, unlike pharmaceutical interventions (Hart, 2009). As described in chapter one, the StepByStep approach to aphasia computer therapy is a complex intervention with multiple components including self-managed practice of therapy exercises on the StepByStep software, tailored by an SLT, with on-going support provided by a volunteer/assistant. In order to understand what measures of fidelity need to be applied to an intervention it is essential to identify all of the key components and how they interact to produce the desired outcomes (Nelson et al, 2012). The StepByStep approach to aphasia computer therapy has been described in the therapy manual (Palmer, 2015; appendix A) and the Big CACTUS trial protocol (Palmer et al, 2017; appendix B). Therefore, the components of the intervention could have been extracted from these documents, however the clinical description was written by only one person (the chief investigator of the Big CACTUS trial) and there are other StepByStep approach experts who might have valuable insights into the intervention's components and how they interact. Furthermore, whilst the manual describes the intervention in detail it does not recommend how to measure fidelity to the intervention. As such, this chapter will explore the components of the StepByStep approach and what should be measured in the fidelity evaluation from the perspective of those with expertise in the intervention. This will enable the fidelity evaluation to be tailored to the intervention as recommended in the literature review (chapter two).

Aims and objectives

The aim of the research detailed within this chapter (study two) was to describe from the perspective of multiple stakeholders the key components of the StepByStep© approach to aphasia computer therapy, how the components interact and how to measure them in order to determine what measures of intervention fidelity should be applied to the Big CACTUS trial. This aim will be achieved by addressing the following objectives:

- describing and visually mapping the key components, supporting components, the interactions between the components and the theory underpinning the StepByStep approach;
- identifying the components that should be measured in order to evaluate fidelity to the StepByStep approach; and
- identifying possible methods of measurement through discussion with key informants.

3.2 METHOD

Study design

A qualitative approach was adopted in order to gather a richness of depth and detail needed to address the explorative research objectives (Mason, 2002). Utilising qualitative interviews with probing questions facilitated in depth discussion about key informant's understanding of the process of delivering and receiving the StepByStep approach to aphasia computer therapy. Furthermore, the exploratory qualitative approach enabled key informants to describe how they would measure components of the intervention in the process evaluation in study three (chapter four).

Setting

Interviews were conducted in-person and over the phone, at the convenience of the participant and depending on their location in the UK. The location of face-to-face interviews was determined by the participant and included the participant's home, the participant's workplace and the author's workplace. The interviews were conducted between February and April 2015.

Sampling

A nominated expert sampling strategy was used to ensure all individuals with expertise in the StepByStep approach were invited to participate (Trotter, 2012). All participants had a role involving regular exposure to the StepByStep approach, as well as meaningful knowledge and information about it and a willingness to convey this information to the interviewer and disclose any biases (Tremblay, 1957). When using an expert sample saturation is reached once the entire expert group have been invited to participate (Trotter, 2012). Whilst the StepByStep software is widely used, there are only a limited number of key informants about the 'StepByStep approach', which includes tailoring of the therapy exercises by a SLT with practice supported by a volunteer or SLT assistant. The aim was to include a variety of perspectives in the sample, including: 1) the software designers, 2) SLTs who use StepByStep regularly, 3) researchers who have evaluated the StepByStep approach, 4) people with aphasia (PWA) and their carers who have helped to design and test the software and have been engaged the StepByStep approach for many years, as well as 4) representatives of the charity Speak With IT, a charity delivering a service similar to the StepByStep approach in West Yorkshire. As there are a limited number of experts in the StepByStep approach many of them were already associated with the Big CACTUS project in some way (e.g. advisory roles, providing the software, working on the pilot study), as a result, the author already knew all of the participants. In an attempt to broaden the sample a

snowball sampling strategy was employed. Participants were asked if they knew anyone else with expertise in the StepByStep approach, but no names were put forward (Tansey, 2007).

Eligibility criteria

The sole inclusion criterion specified that participants must have expert knowledge about the StepByStep approach as a designer, user, carer, researcher, volunteer or practitioner. PWA were excluded if they were unable to comprehend two key words in a sentence (see consent process) because it would have been unlikely they would have fully understood what was being asked of them, even with support.

Recruitment and consent

Potential participants were contacted by email, including a brief summary of the study with the information sheet attached. If they were interested in being interviewed about the StepByStep approach they were asked to contact the author. The consent process differed depending on whether the potential participant had aphasia. Participants who did not have aphasia were provided with an information sheet and consent form and given the opportunity to ask questions. If they chose to participate they were asked to sign the consent form. If the participant had a communication impairment the author used Palmer and Patterson's (2011) approach to obtaining consent from PWA, as such interviews with PWA took place in-person. The Consent Support Tool (Palmer & Jayes, 2016) was used to determine how many key words participants were able to understand in a sentence. If the participant understood complex sentences, the standard participant information sheet sufficed. If they could comprehend at least two key words in a written sentence, the accessible information sheet was provided and if they chose to take part, they were asked to sign the accessible consent form.

Ethical approval

Ethical approval was obtained from the Research Ethics Committee in the School of Health and Related Research at the University of Sheffield (see appendix D).

Data collection

Participants were interviewed about their understanding and experience of designing, delivering and using the StepByStep approach. The interview schedule was developed to facilitate discussion around what participants perceived to be the key components and supporting components of the StepByStep approach, how they interact with one another and

how they can be measured. The questions from the interview schedule, detailed in table 3.1, were asked flexibly using prompt questions and amending the order where necessary to ensure it felt like a ‘conversation with a purpose’ (Burgess, 1984). As well as providing a verbal response to the questions, participants were invited to write down the key components and supporting components, so they could refer back to them and move them around to demonstrate relationships. Post-it notes were used in face-to-face interviews and the ‘Google Drawings’ when the interview was conducted over the phone (shared on Google drive so the interviewer could see it in real time). ‘Google Drawings’ operated in a similar way to post-it notes, participants could select different coloured shapes, write on them and move them around the screen (see figure 3.2). Post-it notes were arranged on large pieces of white paper and participants were free to choose how to group the items to reflect their different functions and how they understood them to interact (see figure 3.3).

Interview schedule questions
1. What beneficial outcomes can the StepByStep approach achieve?
2. What do you think are the key components of the StepByStep approach? The things that actively lead to the beneficial outcomes?
3. What are the theories/ principles/ ideas that underpin each of the key components?
4. What other components need to be in place to support each of the key components?
5. How do the key components and other components interact?
6. In order to find out whether all of the key components and supporting components that make up the StepByStep approach have been delivered in the Big CACTUS study we need to measure them.
a) Do you think X can be measured?
b) How do you think X can be measured?
7. Which do you think are the most important components?

Table 3.1. Interview Schedule to establish the key components and methods of measuring the StepByStep approach to aphasia computer therapy

Prior to the interview taking place the author shared the therapy manual for the ‘StepByStep computer therapy approach for the NHS’ to prevent any misunderstandings about what the author meant by the term ‘StepByStep approach’. The interviews lasted approximately one hour. At the start of the interview, a pro forma was used to collect descriptive data about the participants, including: gender, age, final level of education, in what capacity they have developed expertise about the StepByStep approach and any biases relating to the StepByStep approach they chose to declare (see appendix E). Joint interviews were offered to PWA if they had a carer who was also familiar with StepByStep. The interviews were recorded using a digital audio recording device and transcribed verbatim by the author.

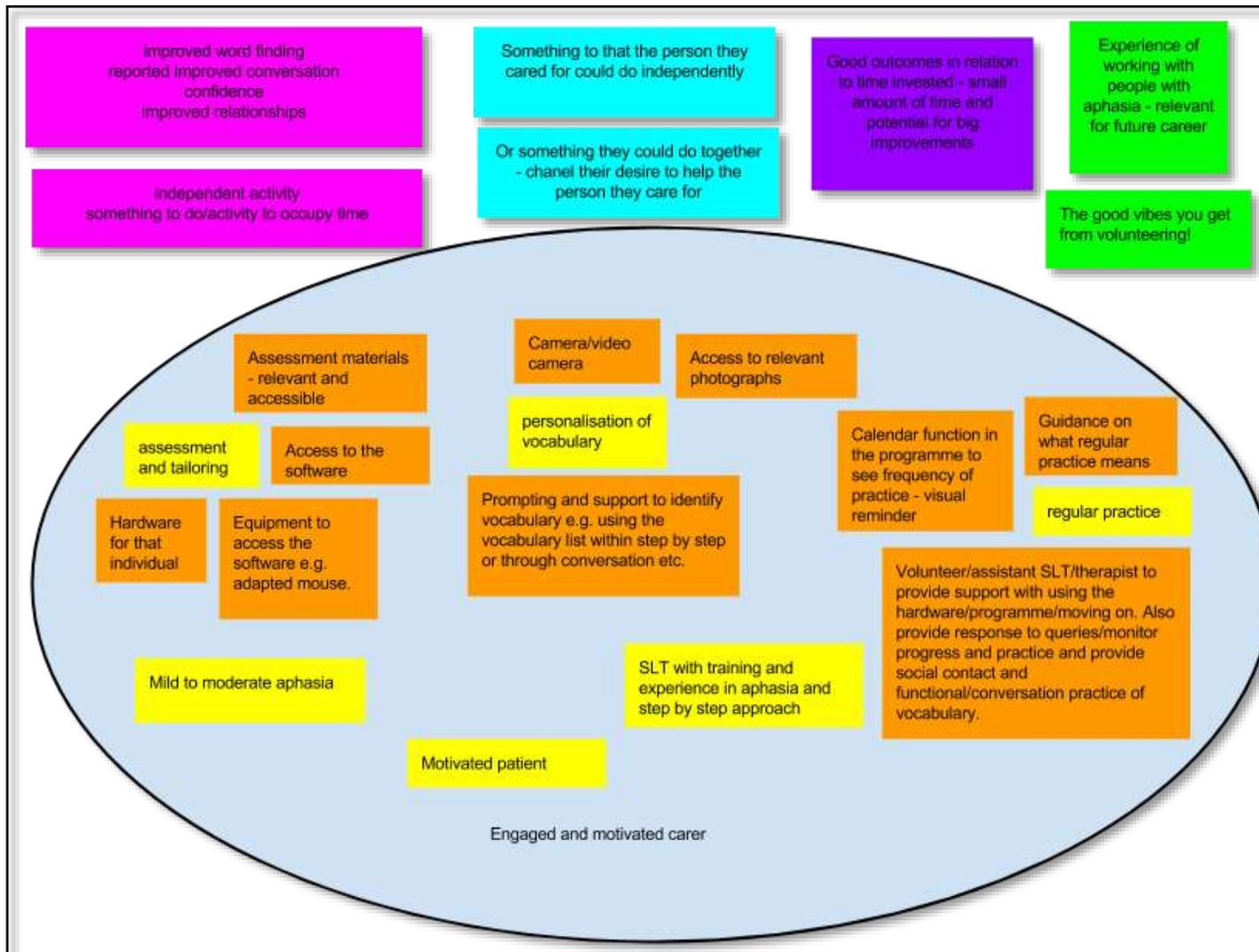


Figure 3.2. A 'google drawings' depiction of the components of the StepByStep approach by S02 (SLT and researcher)

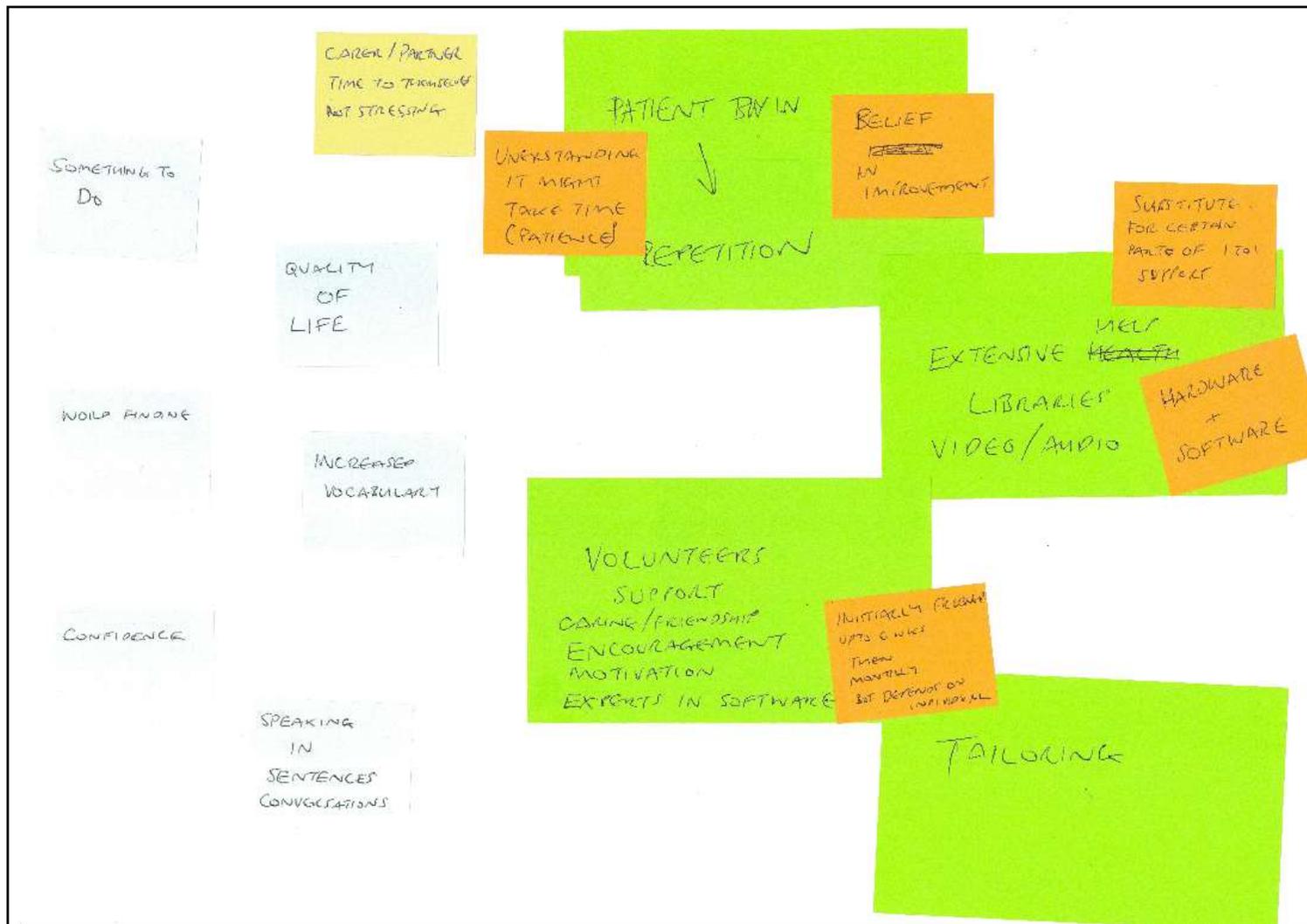


Figure 3.3. A post-it note depiction of the components of the StepByStep approach by S05 (volunteer)

Secondary data collection

Preliminary data analysis demonstrated that key informants perceived a diverse range of aspects of the StepByStep approach should be measured in order to establish whether it had been delivered as intended. It would not have been feasible to measure all of the aspects of the intervention identified by key informants, due to time and resource limitations. To ensure the measures chosen to be collected in the Big CACTUS trial were the most important and meaningful according to key informants from various perspectives, feedback was sought from the participants. A summary of all of the items the participants thought should be measured was returned to all of the participants that took part in the initial interviews for feedback. Participants were asked to select the 10 most important items to measure and to rank them from 1-10 (1=most important).

The reason for selecting 10 was that a secondary use of the measures was to identify which intervention components were associated with improved outcomes in the component analysis in study five (chapter six). 10 was the maximum number of variables that could be included in the component analysis, based on the 1 factor per 10 participants rule of thumb proposed by Harrell et al (1996), since it was anticipated 95 participants would be randomised to the computer therapy group in the Big CACTUS trial.

Data analysis

The interviews were analysed using a six stage process of thematic analysis, which involves familiarisation, iteratively developing an initial coding framework, identifying themes, reviewing themes, naming and defining themes and writing up the findings (Braun & Clarke, 2006). Familiarisation was achieved through transcribing and reading the interview transcripts. A deductive approach was adopted in the early stage of analysis, meaning the questions from the interview schedule informed the higher order themes. Subsequently codes emerged from the data that allowed exploration of different interpretations of the StepByStep approach. Analysis of transcripts and visual data (e.g. diagrams of StepByStep approach) were managed in NVivo 10 (QSR International, 2012). The similarities and differences between different participants' understanding of what the components of the intervention were and how they interacted was recorded. The process of reviewing and defining the themes and sub-themes resulted in the key components being defined as themes and the development of a framework depicting the StepByStep approach components and how they interact.

Secondary data analysis

Participant's responses from the secondary data collection were returned ranked from 1-10 with 1 being most important, however in order to sum the ranks it was necessary to transform them into a score (i.e. numbers reversed so 10 becomes the most important). The scores for each item from each participant were summed and the items were ranked according to their total score, thus demonstrating the relative importance of measuring each item according to the sample of expert participants.

3.3 RESULTS

Participants

Eight StepByStep approach experts were invited to participate and seven responded and agreed to participate. The seven participants took part in five individual interviews and one joint interview with a participant with aphasia and their carer (see table 3.2 for individual participant details). Three of the interviews took place over the phone and three were carried out in person at the participant's home, the participant's workplace and the author's workplace. Four of the participants were female and three were male. The median age of the participants was 49 (ranging from 32-56). Six participants were white British and one participant was white and Asian. All participants were educated to a high level, having some post-school education, with four having completed higher degrees, such as a PhD.

All participants used the StepByStep software frequently with usage varying from daily to bi-weekly. The median length of time working with or using the StepByStep software was 7 years (ranging from 2.5 to 15 years). Participants were asked what their role was in relation to the StepByStep approach and five participants had more than one role, which is further evidence of their expertise. All of the potential roles identified a priori by the author and listed on the interview pro forma (SLT using the StepByStep approach with PWA, PWA who uses the StepByStep approach, relative or informal carer of StepByStep user, volunteer supporting PWA to use the StepByStep approach, designer and researcher) were selected by at least one participant demonstrating the wide range of expert perspectives included. Biases were declared by the designers who have a financial stake in the software, by the Chief Investigator of the Big CACTUS study who is currently evaluating the StepByStep approach and by the PWA and carer participants who provide advice to the designers, but have no financial stake in the product.

During the interviews participants reflected on their expertise when describing prior experiences of using or delivering the StepByStep approach in order to qualify their opinions. Furthermore, the majority of participants spontaneously discussed their role and position in relation to the StepByStep approach early in the interview, which was particularly revealing when a participant had more than one role in relation to the StepByStep approach.

“And it’s interesting-, it might be worth you knowing that I’m very much think about this from the perspective of delivering this myself on the NHS as a clinician and I’m not desperately thinking about this in my role of chief investigator, obviously it’s still going to affect things.” S01 SLT, researcher and designer

Key informant ID	Interview type	Age	Gender	Final level of education	Ethnic group	Role in relation to StepByStep (SBS) approach	Years working with StepByStep approach	Frequency of StepByStep use	Biases to declare in relation to StepByStep approach
S01	Individual & face-to-face	38	Female	Higher degree	White British	SLT using SBS approach with PWA, Designer, Researcher	5	Weekly	Chief investigator on study to evaluate approach
S02	Individual & over the phone	32	Female	Degree	White British	SLT using SBS approach with PWA, Researcher	6	Weekly when using with a client	None
S03	Joint & face-to-face	56	Male	Diploma/certificate in higher education	White British	PWA who uses the SBS approach for own rehabilitation	7	Everyday	Works with Steps Consulting in development, but no financial interest
S04	Joint & face-to-face	54	Female	Diploma/certificate in higher education	White British	Relative or informal carer of SBS user, Volunteer supporting PWA to use the SBS approach	7	2 or 3 times per month	Works with Steps Consulting in development, but no financial interest
S05	Individual & face-to-face	39	Male	Higher degree	White & Asian	Volunteer supporting PWA to use the SBS approach	2.5	Daily	None
S06	Individual & over the phone	49	Female	Higher degree	White British	SLT using SBS approach with PWA in independent practice, Designer, Researcher	10	Daily	Developer with financial interest
S07	Individual & over the phone	49	Male	Higher degree	White British	Designer, Evaluator monitoring usage from a business and independent therapy practice perspective	15	Bi-weekly	Ownership of StepByStep (e.g. financial interest)

Table 3.2. Participant demographic information and familiarity with the StepByStep approach

Findings: key components of the StepByStep approach

The thematic analysis identified four key components of the intervention which have been analysed as themes: 1) the StepByStep software, 2) therapy set-up: personalising and tailoring the StepByStep software, 3) regular independent practice, and 4) supporting and monitoring use. Additional themes, separate to the key components, included the perceived outcomes of the StepByStep approach and measuring the components and processes of the StepByStep approach.

There was variation in what participants perceived to be the key components of the StepByStep approach, as anticipated due to the different positions of the participants in relation to the StepByStep approach. Some described the approach in relation to the person or object that enables an activity to take place (e.g. SLT), whereas others described the behaviour or activity that needed to be carried out without specifying who needs to fulfil that role (e.g. tailoring of the intervention). During the analysis process it was decided that the data would be described in terms of the behaviour or activity with reference to who might usually perform the task, due to inconsistency in participants' perceptions about who should perform different activities.

In response to the final question on the interview schedule each participant wrote a list of what they perceived to be the most important components in the StepByStep approach (see table 3.3). Participants wrote lists of 3-6 items and there was much overlap between the components selected by different participants. This information was useful whilst concentrating the analysis and establishing which components should be described as key components.

Components perceived to be most important by the key informants	Number of key informants selecting each component (total=7)
Personalised/functional/useful pictures and words	5
Motivation/ PWA buy-in	4
Regular independent practice	4
Supporting use	4
StepByStep software/ technology	3
Speech and language therapist skill	3
Setting-up therapy tailored to the participant	3
PWA	2

Table 3.3. Number of key informants selecting each component based on perceived importance

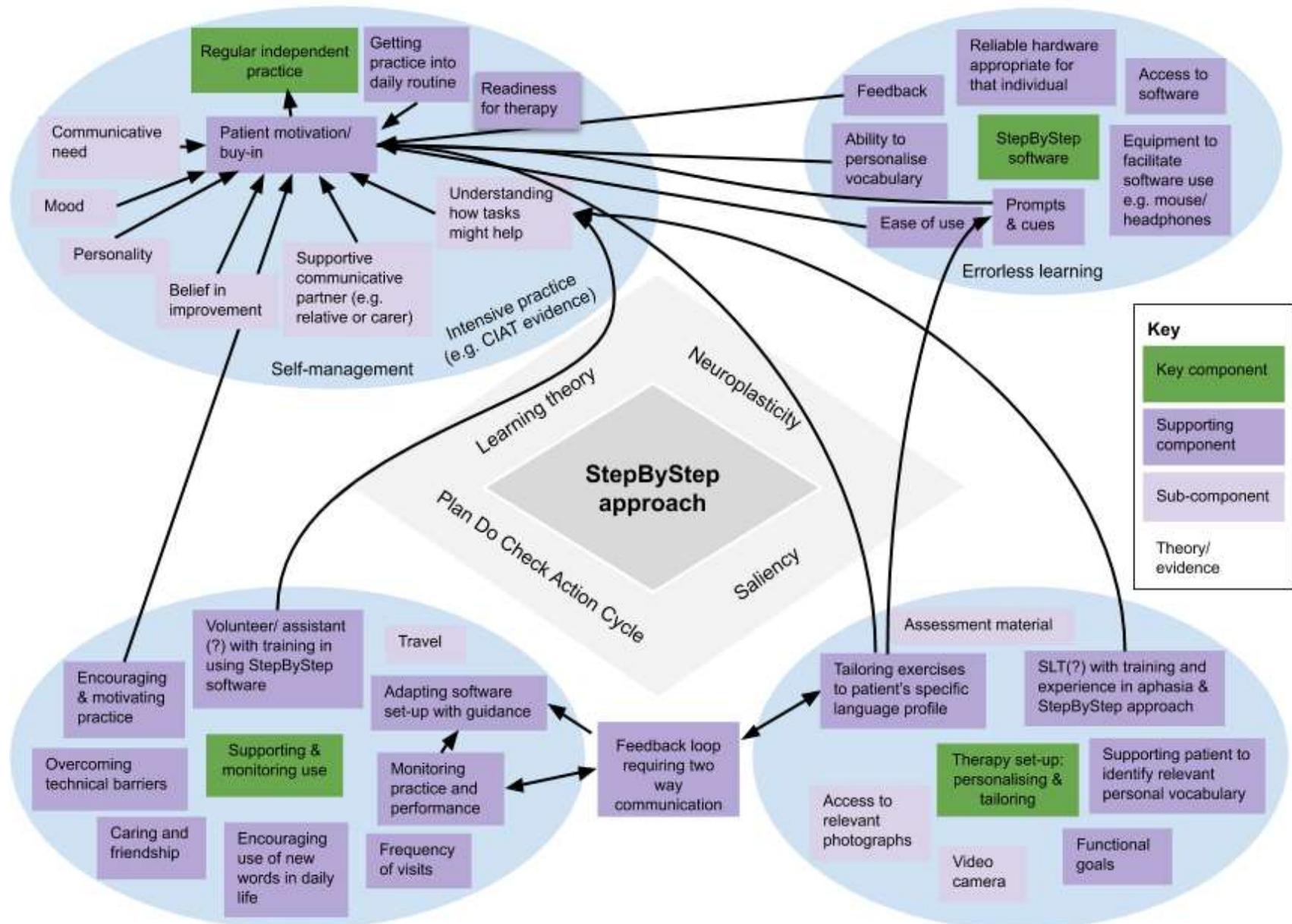


Figure 3.4. Diagram of the StepByStep approach to aphasia computer therapy

The key components, supporting components and their interactions as well as the theories and evidence underpinning the approach are detailed in figure 3.4. The diagram was initially developed as an amalgamation of the participants' diagrams that were produced during the interviews (see figures 3.2 and 3.3 for examples). Theories or evidence underpinning the approach and interactions between components have been added subsequently during the thematic analysis. The arrows indicate relationships between components described during the interviews. The uni-directional arrows show a one-way relationship and the bi-directional arrows are indicative of a two-way relationship. The diagram has been developed and refined throughout the analysis process. Each of the key components is now described in turn alongside their supporting components and any theories identified by participants. The size of the key components on figure 3.4 is indicative of the focus placed on the four key components by the key informants. Regular independent practice is the largest because key informants perceived it to be integral for the intervention to achieve its desired outcomes, whereas the smallest is the StepByStep software reflecting that a minority of participants explicitly discussed the software (as they assumed its presence), focusing instead on specific features that impacted upon other components.

The StepByStep software

A volunteer described in lay terms their understanding of what the StepByStep software is:

“StepByStep [...] is a conversion of genuine speech and language therapy exercises that were paper based and have been made into something that can be used on a computer.” S05 Volunteer

Whilst the StepByStep software underpinned all participants' narrative when discussing the key components of the StepByStep approach only a minority of participants explicitly described it as a key component and those that did focused on its accessibility. Resources are required to purchase software and hardware in order for it to be accessible and both the software and the hardware need to be functioning.

“So the software has to be there so that people can practice.” S01 SLT, researcher and designer

Much of the dialogue about the StepByStep software concentrated on the features of the software that motivated and encouraged use, such as how easy the software is to use, the prompts and cues it provides, the feedback it provides on practice time and performance and the capacity to personalise vocabulary.

“Well I just think it’s so easy to use the program.” S04 Carer and volunteer

“I think the other thing the software does in terms of motivation is the feedback that it gives itself, feedback on success, which should help with motivation, in theory.” S01 SLT, researcher and designer

“The beauty of StepByStep is it can be tailored to peoples’ interests and hobbies.”
S05 Volunteer

Whilst the capacity of the software to be personalised was perceived to be motivating, this is something the PWA is likely to need help with and was therefore categorised as part of a separate theme called therapy set-up. The main supporting components for the StepByStep software was having appropriate and reliable hardware for that individual and having equipment, such as a mouse or a microphone, to facilitate software use to meet the needs of individual PWA.

“You would need the appropriate hardware for that individual as well, whether that be a PC or a laptop or a tablet, and with the relevant equipment, so that if they have a physical disability they would be able to access and operate the program.” S02 SLT and researcher

Contextual differences in the barriers to having the appropriate technology were acknowledged and this was one area where delivering this approach in the NHS, rather than independent practice, demonstrated a significant disadvantage.

“We set up computers for people with aphasia in a particular way to make it easy for them to access and computers aren’t necessarily set-up in that way when they’re delivered by the NHS. In fact actually quite often they’re set up in a really unfriendly way by an IT department who don’t really understand the difficulty that someone with aphasia might have.” S07 Designer and evaluator

The key theory underpinning the StepByStep software itself is that of errorless learning. The stepped approach starts with tasks that can be more easily achieved before moving on to more difficult tasks, however this can be enhanced through SLT involvement in tailoring the software.

“Although that errorless learning and that stepped approach is still built into the software, so to an extent it would do it on its own, but perhaps we can do it even more sensitively if there’s a speech and language therapist involved.” S01 SLT, researcher and designer

Therapy set-up: personalising and tailoring the StepByStep software

Whilst the software provides the facility to add personal vocabulary, the addition of personal vocabulary was described as part of therapy set-up. PWA and carer participants felt that familiarity enabled the participant to recognise items more easily making the re-learning process easier.

“Because you couldn’t tell what the picture was, whereas because it’s a photograph you know exactly what it is and if it’s your own kettle then it takes away some of the confusion because it’s something you’re familiar with.” S04 Carer and volunteer

Participants described the vital role of the PWA in choosing personal vocabulary, however the SLT participants also focused on the importance of the words being functional or useful in the PWA’s everyday life. Disparity was apparent in participants’ interpretation of the word ‘personal’. Some concentrated on the participant actively choosing the words themselves, whereas others felt that the words needed to be *“relevant in their life”* but placed less weight on the participant being involved in that decision. Participants also discussed the practical requirements for personalisation including access to relevant photographs and access to a video camera to record prompts and cues for personal words. Clinical participants described the importance of salience in the learning process as one of the theories underpinning therapy set-up.

“There is a lot of evidence that at this long term stage people are able to learn what they practise, but not necessarily to generalise that to lots of other things, so that is so important that we’re practising the things we need to use.” S01 SLT, researcher and designer

The type and level of difficulty of the exercises on the StepByStep software can be tailored to the PWA’s needs. Establishing the most appropriate level of difficulty was perceived to require *“formal and informal assessment”* of the individual’s language impairment. Tailoring the exercises was perceived by most participants to increase the effectiveness of the therapy because it would *“motivate practice and stimulate learning”*. The process of tailoring the StepByStep software was thought by some to require the skills of a SLT, but volunteers also described performing this role. Both SLTs and volunteers acknowledged that it was essential to be knowledgeable about the StepByStep program and it was acknowledged that this required training. SLTs and volunteers discussed the benefits of experience, but SLTs referred to years of experience, whereas the volunteers described the number of visits they had conducted.

“So in terms of the kind of assessment and tailoring, so you would need a qualified speech and language therapist and you would need access to the correct assessment materials or relevant assessment materials. I guess you would need a speech and language therapist with some experience in diagnosing and identifying somebody’s level of impairment and then experience and knowledge in how to tailor the program.” S02 SLT and researcher

“So it gets to the point that I’ve done 76 client visits now, so I feel I’ve got quite a bit of experience.” S05 Volunteer

Participants described an interaction between tailoring the type and level of difficulty of the exercises and the theme of monitoring and supporting use, because it was only through monitoring that inappropriate set-up for the individual PWA could be identified. In instances in which these roles are performed by different people it creates an additional requirement for two-way communication between the therapist and the person supporting use.

“That’s a process of supporting the volunteer or assistant so they can adequately support the patient, so that needs to be an ongoing process through some kind of feedback loop.” S01 SLT, researcher and designer

Regular independent practice

As a self-managed intervention people perceived repetitive, regular, independent practice to be an essential component of the intervention to allow the desired outcome to be achieved.

“The therapy is relying on repetitive intensive practice and if you’re not doing repetitive intensive practice then the chances of it working are pretty slim.” S07 Designer and evaluator

All of the participants recognised the importance of the PWA being motivated or ‘buying-in’ to the StepByStep approach to ensure that regular independent practice occurs. Some participants discussed motivation in relation to the individuals’ personality or linked to other internal factors, such as mood or a need for greater communication.

“This therapy is hard therapy and so if their communicative need isn’t there then I find that they’re not going to be as motivated and they’re not going to do it as intensively as is required really.” S06 SLT, researcher and designer

Whereas others focused on how external factors related to the intervention can influence motivation, for example the SLT and supporters were perceived to play a key role in

ensuring the therapy was set up appropriately, explaining how the intervention works and the process of recovery as well as providing positive or negative reinforcement.

“What we can do is provide motivation and encouragement and ensure by understanding the software that we are setting exercises accordingly to what the person needs.” S05 Volunteer

“Sometimes it’s a positive thing, it’s about engaging with that person and getting positive feedback from them on how well they’re doing and wanting to please and that kind of thing. For some people it can be slightly effective, but more negative. It can be about not wanting to let people down.” S01 SLT, researcher and designer

Another factor related to regular practice identified by participants who had volunteered to support PWA using the software was the importance of getting practice into the PWA’s daily routine.

“Carer and volunteer S04: So find somewhere you can fit it in your routine to do it and I think that’s what made it work for you was that you found a place to put it in your daily routine.”

PWA S03: Wii fit, you know and computer.

Carer and volunteer S04: And that’s what you do of a morning, unless we’re going it out and then you can’t wait to get back to do your computer.”

In addition, some components of the software itself were thought to influence motivation and therefore the amount of practice the PWA would perform. These included whether the software was working properly, the calendar function showing the amount of practice, the ability to personalise the vocabulary and providing reinforcement through feedback.

“I mentioned stimulating motivation and I think the other thing the software does in terms of motivation is the feedback that it gives itself, feedback on success, which should help with motivation, in theory.” S01 SLT, researcher and designer

Participants discussed the importance of regular independent practice in relation to the theory of neuroplasticity, although participants without clinical knowledge did not use this terminology they were able to explain in lay terms how they understood this process to work.

“I can’t justify this scientifically, but it seems to me that you’re re-programming the brain and therefore it can’t be done irregularly and it can’t be done erratically. I consider the brain to be a muscle and if you were training any other muscle then you’d have to do repeated exercise on that muscle and you’d have to increase, if we

talk about weights for example if you were doing a bicep exercise you'd over time have to increase the difficulty by increasing the weight or the repetition to actually have an impact." S05 Volunteer

Other participants with clinical knowledge also made reference to the evidence from the literature to support the effectiveness of intensive practice from Constraint Induced Aphasia Therapy. The majority of beneficial outcomes for the PWA and their carer were described as the result of practice. Beneficial outcomes were seldom discussed in relation to the other key components.

Supporting and monitoring use

Supporting and monitoring use of the software was the component with the widest variety of interpretations, due in part to differences in opinion about who should deliver this support. Those working in independent practice felt that the role of on-going support needed to be provided by a qualified therapist, whereas those delivering and receiving the intervention through the NHS or voluntary sector were comfortable with a volunteer trained to use the StepByStep software fulfilling this role, with or without the support of a SLT. This was a point of contention for those delivering the StepByStep approach in independent practice because they perceived the monitoring and adjustment of the StepByStep approach to require clinical skills to be utilised within a Plan Do Check Action (PDCA) cycle which is an iterative cycle used for quality control that originated in industry.

"I think that needs the speech and language therapist to say OK this patient is having problems with the therapy because of this we're going to adapt it to that and try again." S07 Designer and evaluator

Irrespective of who was providing the support there was agreement around the activities required to support use and it was acknowledged that the activities required depended on the needs of the individual PWA. Activities included: enabling the PWA to use the software by helping to overcome technical barriers, building a supportive motivational professional relationship or friendship, monitoring practice and performance, adapting the software when required and using words targeted by the programme in conversation to aid generalisation.

"It's really just giving encouragement and trying to stop there being problems so that the person who's using it hasn't got the problems to sort out really, being one step ahead." S04 Volunteer and carer

“Someone going along regularly and being someone that cares, I think that in itself, just someone that cares and forming a friendship.” S05 Volunteer

Views regarding the frequency with which support was required varied amongst participants, but there was agreement about the importance of providing support when needed by the PWA and this was perceived to require more frequent visits initially with the frequency diminishing over time for most PWA.

“It is individualised, as a rule of thumb quite regularly for the first 4-6 weeks and then spread out to once a month.” S05 Volunteer

Ensuring and increasing the PWA’s motivation to practise was perceived to be one of the main reasons for support to be provided.

“So I think that motivation, that interaction with another human being can just really help engage and therefore motivate somebody to practise.” S01 SLT, researcher and designer

Participants discussed motivational devices such as practising to *“please other people”*, practising out of a sense of obligation because *“somebody’s coming to see how I’m getting on”* or practising to *“avoid disapproval”*. Others focused on the supporters’ role in explaining how an exercise is beneficial and adapting the software to ensure it challenges the PWA at an appropriate level.

“I guess you could equate it to having a personal trainer in fitness. As much as anyone thinks they can push themselves when they’re doing exercise you can never push yourself as much as somebody else would, it’s exactly the same thing, the difference is we are experts in the software so we know what’s available and we know how to get the best out of it.” S05 Volunteer

The other key reason to provide support was to aid generalisation from naming words on the computer to using them in everyday life. Participants were in agreement that this was the role of volunteers or therapy assistants or family carers if available. Participants either discussed encouraging PWA to use the words in functional scenarios or a specific task referred to as the *“CIAT game”*, which requires the target words/images to be printed and the PWA has to ask the supporter for the target.

“We don’t want a situation where someone puts lots of time in on the computer, gets better at naming the pictures on the computer, but that last step is missing in the approach and they don’t get the functional benefit that they potentially could get if

they did the CIAT game and that's where the use of volunteers comes in there." S06
SLT, researcher and designer

Sub-components specific to those working with volunteers or therapy assistants were the benefits of the volunteer having their own transport, the need to support the supporters, the need for two-way communication between the supporter and the SLT.

"There has to be a good enough relationship that the volunteer feels OK about discussing with the speech and language therapist if something isn't going to plan."
S06 SLT, researcher and designer

Some of the participants felt that on-going support was not a requirement for all PWA, particularly those who are *"familiar with technology"* and *"people with milder difficulties"*.

"You see for some people I would say that it's essential that they had support with the on-going use of it, but for others that would be supportive, but not essential." S02
SLT and researcher

Findings: outcomes and fidelity measures

This second findings section describes two further themes including: 1) the beneficial outcomes participants perceived to be achieved by delivering the key components of the intervention and 2) what the key informants thought was important to measure in order to understand how the therapy was delivered in practice.

Outcomes of the StepByStep approach

A distinction was made between the different outcomes that benefitted the main stakeholders involved in delivering and receiving the intervention. The spider diagram in figure 3.5 shows the various outcomes for all of the individuals involved including the PWA, the relative or carer, the SLT and the volunteer. Only the outcomes relevant to the PWA are described narratively.



Figure 3.5. Diagram depicting the perceived outcomes of the StepByStep approach for all stakeholders (key: blue=PWA, orange=relative/carer, red=volunteer, green=SLT)

It was suggested that the outcomes for the PWA could be at “different levels” and that there could be beneficial outcomes for the PWA whether or not their language actually improves. The opportunity to carry out regular language based tasks was perceived to be beneficial for the PWA because it gave them something to do and a sense of purpose.

“Interviewer: *How has StepByStep helped you?*

PWA S03: *StepByStep means to me...well...you know...I don't know.*

Carer and volunteer S04: *Can you put it in words?*

PWA S03: *Busy.*

Carer and volunteer S04: *You mean it's given you something to do?*

PWA S03: *To do, yeah. Too true.”*

Other outcomes including improved confidence and independence were also perceived by some to be achievable regardless of whether their language ability actually improved. Participants discussed independent activity affording a sense of autonomy and this being one of the benefits of the StepByStep approach being a self-managed intervention.

“A lot of these people can’t do much by themselves and the use of the computer can make them actually be able to be independent which is clearly important to a lot of people who have previously lived very independent lives.” S01 SLT, researcher and designer

Independent practice was also perceived by some to increase the PWA’s confidence, but others linked the improvement in confidence directly to an improvement in word-finding ability or to the regular interaction with a volunteer. All participants described improved confidence as one of the outcomes of using the StepByStep approach.

“Structured computer therapy using the StepByStep approach can increase people’s confidence and that will hopefully relate to being a more confident communicator and using their language more in everyday life.” S06 SLT, researcher and designer

Participants reflected on the variety of language impairments resulting directly from brain damage that the StepByStep approach can be used to rehabilitate, including word-finding, using words in sentences, reading and writing impairments, consequently producing different outcomes for different people.

“So I would say the outcomes obviously vary by each person and the aphasic disabilities they have.” S05 Volunteer

Moving beyond the direct impairment, participants went on to look at wider social impact, such as improving their conversational ability in everyday life thereby enabling the PWA to engage in meaningful relationships with family and friends.

“It gets you more involved with life and everything we’re doing” S04 Carer and Volunteer

Measuring the components and processes of the StepByStep approach

The broad similarity in the key components and supporting components identified by participants also resulted in similar measures being identified by different participants. Most participants referred back to their StepByStep approach diagram and described how they would measure each of the key components and some of the supporting components. Nineteen components or supporting components that were important to measure were described in the interviews. These are presented in table 3.4, grouped according to the key component they are related to, alongside a supporting quote that either illustrates perceived importance or includes a suggestion for how the component should be measured (i.e. a proposed method for measurement).

Potential components to measure identified from interviews	Supporting quote
<i>The StepByStep software</i>	
Availability of the software (during the time the PWA should have the software)	“Yeah I think that always available one is something that needs-, is very important obviously and needs to be measured about whether it is actually available, whether they do actually have it.” S01 SLT, researcher and designer
Ease of use of the software	“Well I suppose ease of use you can measure how many times a client rings you up to say I’ve forgotten how to do it.” S04 Carer and volunteer
Appropriate technology (e.g. hardware) to enable practice	“A technology survey really, what was the equipment that was used?” S07 Designer and evaluator
<i>Therapy set-up: personalising and tailoring the StepByStep software</i>	
What sequence of steps are selected and why (e.g. justification for tailoring)	“I think what might be a good idea is to almost have two or three speech and language therapists, looking-, you know independent speech therapists who work with this population looking at what decisions people have made, not to say ‘this is right’, but more to pick up whether there is anything glaringly strange.” S01 SLT, researcher and designer
How much have the words/photos been personalised	“Looking at the therapy that was delivered how many items appeared in the ‘new items’ list for a client, so that could be a measure for you.” S06 SLT, researcher and designer
How much time was spent setting therapy up (e.g. frequency and duration)	“You could deliver therapy to somebody without a lot of input for them, so the return for your time investment is probably better than other therapy approaches” S02 SLT and researcher
How skilled is the person assessing the PWA and setting up the software	“So you can check with them in two ways, you can check with them after the training, whether on paper they can tell you what it is they think they should be doing, but you can also check partly in whether they are doing what they think they should be doing.” S01 SLT, researcher and designer
Quality of communication from the SLT to the supporter (volunteer or assistant)	“So I think that’s important to check how well the therapist are engaging in that process as well and I guess the easiest way to do that would be to check records, most likely to be emails” S01 SLT, researcher and designer
How are the steps adjusted or adapted in response to the PWA’s performance	“So they need to try it and check whether their hypothesis is correct and if their hypothesis isn’t correct then they need to further adapt it and that’s really the therapist being the manager. The therapist is managing that therapy process, they’re managing the volunteer too, on the basis of feeding back changes to the volunteer.” S07 Designer and evaluator

<i>Regular independent practice</i>	
PWA motivation/buy-in	"I mean the other way of measuring this motivation is how many of the group that received the therapy want to carry on with the therapy afterwards, that's going to be an indication of motivation." S06 SLT, researcher and designer
How much people practice (e.g. frequency and duration)	"So that component of intensity and repetitive practice can be measured through the software itself." S06 SLT, researcher and designer
What do people practice (e.g. content)	"So I suppose the overall time and the pattern and whether they've adhered to different steps that's collected by the key file" S07 Designer and evaluator
PWA's performance on the steps that record response	"Whether progress is being made that is actually online on each step the results are shown in terms of graphs or whether there is a correct response or not, you get graphs of progress over time" S06 SLT, researcher and designer
Generalisation to everyday life (do they use/practice the words away from the computer)	"Sometimes to actually write down when they hear the words being used, keep a bit of a diary away from the computer to see whether this is increasing over time" S06 SLT, researcher and designer
<i>Supporting and monitoring use</i>	
How much support did the PWA receive (e.g. frequency and duration)	"Yeah I think, so kind of the frequency and quantity of support being offered" S02 SLT and researcher
What type of support was provided (e.g. content)	"Recording the general type of support that they were giving" S02 SLT and researcher
Competence of the person (volunteer or assistant) supporting the PWA	"Potentially therefore checking that they are doing that, not just that they've been trained to do it, but they are doing those things that they've been trained to do." S01 SLT, researcher and designer
How good is the relationship between the supporter (volunteer or assistant) and the PWA	"I can visibly see that I'm forming friendship and it's obvious but I don't know how you'd measure it so much" S05 Volunteer
Quality of communication from the supporter (volunteer or assistant) to the speech and language therapist	"Having regular feedback from the volunteer to the speech and language therapist, how is it going" S06 SLT, researcher and designer

Table 3.4. Components and supporting components of the StepByStep approach identified as important to measure. Supporting quotes either illustrate perceived importance or include suggestion for how the component should be measured.

Feedback was sought from the participants to reduce the number of aspects of the intervention that should be measured in the process evaluation of the Big CACTUS trial (chapter four) and the component analysis (chapter six), from nineteen to a more manageable number of ten. All nineteen aspects have been described in the participant interviews and reduced in number through a ranking exercise (for details of the methods see the secondary data collection and secondary data analysis sections; pages 76-77). Only five of the seven participants provided feedback. The PWA and carer that were interviewed jointly provided one joint feedback score. One participant awarded several components the same rank. The ten aspects of the intervention selected for measurement by the interview participants are detailed in table 3.5. The table includes participants' individual scores and the total summed scores for the top ten components.

Components selected to be measured in the Big CACTUS trial	S01	S02	S03 & S04	S05	Total
PWA motivation/buy-in	9		10	10	29
How much people practice (e.g. frequency and duration)	7	7	7	5	26
Ease of use of the software	8		9	9	26
What do people practice (e.g. content)		6	8	5	19
How are the steps adjusted or adapted in response to the PWA's performance		9	4	5	18
How skilled is the person assessing the PWA and setting up the software		10		5	15
What sequence of steps are selected and why (e.g. justification for tailoring)	3	5	5		13
How much have the words/photos been personalised	5	8			13
How good is the relationship between the supporter (volunteer or assistant) and the PWA	4	4		5	13
Availability of the software (during the time the PWA should have the software)	10				10

Table 3.5. Aspects of the intervention perceived by participants to be most important to measure in the Big CACTUS trial in order to explore the process of delivering and receiving the StepByStep approach²

² Rank provided by participant was transformed into a score (10 is most important; see methods)

The aspects of the intervention the participants perceived to be most important to measure to find out more about the process of delivering and receiving the StepByStep approach were spread across the four key components, which will enable a comprehensive description of the approach when applied to the Big CACTUS trial. In some instances participants had suggested how the component should be measured during the interview and that informed the decision about how to measure, however it was also necessary to consider the validity of the proposed measures and whether they were practical to embed within the trial.

3.4 DISCUSSION

The findings demonstrate that the StepByStep approach to aphasia computer therapy was considered by expert participants to comprise four key components: the StepByStep software itself, therapy set-up (including tailoring and personalising the software), regular independent practice, and supporting and monitoring use. Multiple supporting components were identified for each of the key components, some of which were more integral than others, for example motivation (a supporting component) to carry out regular independent practice (a key component) was the most interconnected component (see figure 3.4) because many aspects of the software, therapy set-up and support have been designed with the purpose of increasing motivation. For example, the software has been designed to make it easy to use, the therapy is tailored to ensure it is at an appropriate level of difficulty to increase motivation and one of the roles of the supporter is to encourage and motivate practice.

The key components and supporting components of the intervention described in the interviews echo existing descriptions of the intervention (Palmer, 2015; Palmer & Mortley, 2011; Palmer et al, 2012; Palmer et al, 2019). This would be expected as two of the experts that have written about the intervention were interviewed for this research. The benefits of exploring the intervention in such detail from a variety of different perspectives was the bringing together of all of the ideas that are discussed in multiple publications into one place and verifying with additional key informants. Furthermore, exploring the intervention in such detail has also allowed perceived relationships between components to be described in more detail. Assembling different perspectives amplifies the differences in expert's perceptions of what the intervention is and how it should be delivered in different contexts. For example, the differences between NHS, third sector and independent practice delivery, and the different people who will take on different roles when delivering the intervention under particular circumstances. For example, respondents delivering the StepByStep approach in independent practice described the importance of SLT skill in performing the

monitoring role, whereas therapists who have delivered the intervention in the NHS utilise volunteers or therapy assistants to monitor and when the intervention is delivered in the third sector it is not only monitored by volunteers, but sometimes the therapy is also set-up by a volunteer. However, the Big CACTUS trial evaluates the StepByStep approach delivered in the context of the NHS as reflected in the therapy manual.

The theories and evidence described by key informants as underpinning the StepByStep approach, or aspects of it, were for the most part described in detail in chapter one. The Plan-Do-Check-Action (PDCA) cycle, also known as a Deming circle, is an iterative four stage management tool for continuous quality improvement (Sokovic et al, 2010) that has not been referred to in previous literature about the StepByStep approach. Originating in the field of business the PDCA cycle has also been utilised in healthcare, however a systematic review found that reported instances of its use in healthcare showed that it is typically inconsistently applied, poorly reported and key principles of the method are neglected (Taylor et al, 2014). In relation to the StepByStep approach the key informants perceived the PDCA cycle to be based within the therapy set-up and monitoring aspects of the intervention and managed by an SLT with contribution from the supporter.

Potential outcomes generated by the StepByStep approach were identified by key informants for all of the stakeholders including the PWA, the carer, the SLT and the volunteer/supporter. The potential outcomes identified in this chapter for PWA and their carers were similar to those identified by PWA and their carers who received the intervention in the CACTUS pilot study, particularly those relating to improved confidence, independence, word-finding and conversation for the PWA, as well as the carer having more time for themselves (Palmer et al, 2013). The Big CACTUS trial only investigated a small number of the outcomes identified in this study. However, the trial did investigate outcomes at different levels as discussed by key informants (word-finding, conversational ability and communication life; see figure 3.5) which mirrors the selection of outcome measures for the Big CACTUS trial. Trial outcome measures follow the International Classification of Functioning, Disability and Health framework of impairment, activity and participation (World Health Organisation, 2001). The impairment level outcome measure involved the naming of personal vocabulary, activity was assessed through a videoed conversation of relevant topics rated using the activity scale of the Therapy Outcome Measure scale (Enderby et al, 2013), as well as a count of the number treated words used in the conversation, and participation through the Communication Outcome after Stroke (COAST) scale (Long et al, 2008; Palmer et al, 2019).

The potential outcomes for carers identified by key informants, such as having time for themselves, improved relationships and better conversations reducing frustration, were not directly measured in the Big CACTUS trial (Palmer et al, 2017). However, the last five questions of the carer COAST (Long et al, 2009) covered related aspects, including how the PWA's impairment affects their family/social life. At six months, carer's quality of life had improved in the computer therapy group compared to usual care, but the improvement was also found for the carers' of participants who received activity/attention control, suggesting that it might have been the increased attention, rather than the computer therapy itself that had the effect (Palmer et al, in press). SLT and volunteer/supporter outcomes were not measured in the Big CACTUS trial. Existing research has explored the volunteers' perspective including a more in-depth qualitative analysis of the perceived benefits of volunteering (Palmer & Enderby, 2016). However, the potential beneficial outcomes for the SLT have not been explored. Suggestions from key informants included SLT job satisfaction and time efficiency. It may be possible to explore how time efficient the therapy is using data being collected during the Big CACTUS study, but further research would be required to find out if SLTs felt it improved job satisfaction.

Implications for studies three, four and five

The aspects of the intervention identified in this chapter as being the most important to measure in a fidelity evaluation, informed the design of studies three, four and five. Key informants identified 19 components that could be measured to investigate how the intervention was delivered and received. A ranking exercise narrowed this down to 10. Of the ten measures of fidelity proposed by key informants, only three were measures of adherence. Typically, measurement of adherence would be the primary element of a fidelity evaluation (Carroll et al, 2007). Therefore, whilst the components listed will all be measured as part of the fidelity evaluation (study three, chapter four), additional measures of adherence will also be included so that the author can document adherence to all four key components of the intervention identified in this chapter. Other factors identified by participants in this study as being important to measure are *potential moderators* of adherence according to the CFIF (Carroll et al, 2007). Motivation, ease of use and the degree of personalisation are indicative of *participant responsiveness* to the intervention. Therapist skill, how the exercises are tailored and adapted, as well as the relationship between the supporter and the PWA provide information about the *quality of delivery* of the intervention. The measures of intervention delivery and receipt identified in this chapter, indirectly informed the intervention variables available for inclusion in the exploration of

adherence in study four (chapter five) and directly informed the components (i.e. variables) included in the component analysis conducted in study five (chapter six) exploring which components of the intervention are associated with improved word-finding.

Strengths and limitations

This study has provided a comprehensive description of the StepByStep approach to aphasia therapy from the perspective of multiple key informants. The use of post-it notes (both paper and electronic) to detail intervention components enhanced the interview by providing a graphic representation of the participants interpretation of this complex intervention, which enabled participants to easily refer back to previously described components and describe relationships between components throughout the interview.

It is possible that the expert sampling strategy did not reach saturation and that there were other StepByStep experts not known to the author. In order to reduce the likelihood of this a snowball sampling technique was also employed, but no other experts were put forward by the participants. All participants were already known to the author as a result of a separate role in the Big CACTUS study, as such there was a potential risk of coercion due to existing relationships, however the study documents made it clear that they should choose whether they wanted to participate and participants were only approached once by email with one follow-up phone call or email. Another limitation of the author's dual role was that some of the participants used the interview as an opportunity to provide feedback on how the intervention was being delivered by therapists working on the Big CACTUS trial. The information gathered during the process of the interview was discussed with the chief investigator of the trial (also the author's supervisor) and they had a follow-up discussion with the participant to address some of the feedback provided during the interview. It would have been preferable for this study exploring the interventions key components and establishing which components needed measuring to have taken place prior to recruitment to the Big CACTUS trial, however the funding for this doctoral fellowship was secured after the trial commenced.

When feedback was sought for which measures should be applied to the Big CACTUS trial two of the participants did not respond to the initial email and it was decided not to follow-up the participants due to unforeseen personal circumstances the author was aware of. It must be acknowledged that their input might have resulted in different components being measured, however having re-visited their interview transcripts there was only one component, generalisation to everyday life, that they highlighted as being very important to

measure that was not selected as a fidelity measure. Furthermore, the use of words in conversation is an outcome measure in the Big CACTUS trial so this aspect was measured for all trial participants (Palmer et al, 2019).

Conclusion

Four key components of the StepByStep approach were highlighted: the StepByStep software itself, therapy set-up (including tailoring and personalising the software), regular independent practice, and supporting and monitoring use, as well as the relationships between these key components and the supporting components. The ten components of the intervention perceived to be most important to measure were identified and will be applied to the delivery of the StepByStep approach to aphasia computer therapy within the Big CACTUS trial to inform an in-depth exploration of intervention fidelity (chapter four) and to explore which components of the intervention are associated with improved word-finding (chapter six).

Chapter Four: A Process Evaluation of the Intervention Fidelity to the StepByStep Approach to Aphasia Computer Therapy in the Big CACTUS Trial

Previous chapters have reviewed methods of evaluating fidelity in stroke rehabilitation research and used qualitative description to define the key components of the StepByStep approach and how they should be measured. The findings from both of these chapters have informed the design of the process evaluation of fidelity to the StepByStep approach to aphasia computer therapy conducted alongside the Big CACTUS trial described in the current chapter. The process evaluation is guided by the Conceptual Framework for Implementation Fidelity (CFIF; Carroll et al, 2007) and the four key components of the intervention identified in the previous chapter. This chapter will be followed by a more in depth exploration of the factors associated with person with aphasia's (PWA) adherence to regular independent practice.

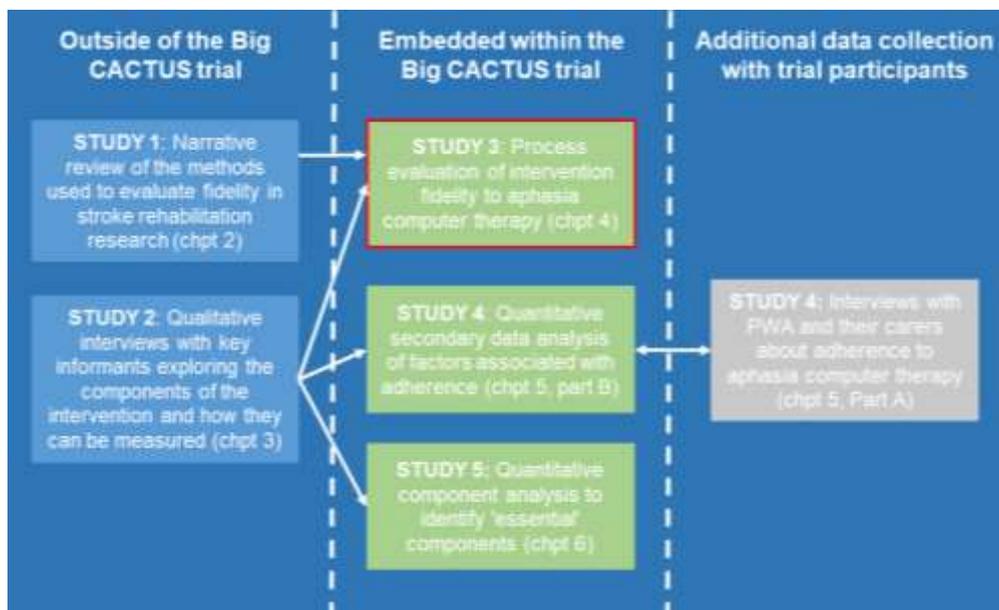


Figure 4.1. PhD structure with red border indicating current chapter

4.1 INTRODUCTION

Medical Research Council (MRC; 2008) guidance on evaluating complex interventions emphasises the importance of evaluating processes, as well as outcomes, in order to understand how interventions are implemented and therefore why an intervention is effective, and how it can best be optimised. As described in chapter one, the effectiveness of the StepByStep approach to aphasia computer therapy was evaluated within a pragmatic, superiority, single blind, parallel group, individually randomised controlled trial called Big CACTUS (Palmer et al, 2019). Process evaluations are commonly used alongside RCTs to assess intervention fidelity. This is particularly important when a complex intervention, such as the StepByStep approach, is being trialled.

MRC guidance on conducting process evaluations of complex interventions defines a process evaluation as “a study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors” (Moore et al, 2015). Process evaluations aim to explore how interventions work, rather than whether they work. As such, process evaluations complement RCTs of complex interventions when it is vital to know how the intervention was delivered, as well as whether it was effective, if the intervention is to be implemented in clinical practice (Moore et al, 2015). Oakley et al (2006) suggest process evaluation is the most appropriate tool for multisite trials where the same intervention can be delivered and received in different ways. It is recommended that researchers conducting process evaluations draw on existing evidence, theory and frameworks in order to understand the processes they expect to take place (Masterson-Algar, 2016).

Aim and objectives

The aim of the process evaluation described in this chapter was to evaluate the intervention fidelity of the StepByStep approach to aphasia computer therapy in the Big CACTUS trial. This was achieved by addressing the following objectives:

- the process of delivering and receiving the StepByStep approach in the Big CACTUS trial was described; and
- the actual delivery was compared to the intended delivery described in the Big CACTUS protocol (Palmer et al, 2017) and StepByStep approach therapy manual (Palmer, 2015).

4.2 OVERVIEW OF METHODS

Design

A process evaluation methodology was adopted in order to evaluate fidelity to the StepByStep approach to aphasia therapy in the Big CACTUS trial. The design of the process evaluation was informed by relevant elements of the CFIF (adherence, quality of delivery and participant responsiveness; Carroll et al, 2007) and the four key components of the intervention identified in chapter three, as well as the recommendations from key informants about how these should be measured. The degree of fidelity with which the intervention was delivered was determined by evaluating how the various components of the intervention were actually delivered compared to the recommendations in the therapy manual (Palmer, 2015) and the Big CACTUS protocol (Palmer et al, 2017). Table 4.1 illustrates the elements of fidelity analysed for each of the four components.

The evaluation has been divided into two sections based on the elements of the CFIF: adherence and moderators of adherence (quality of delivery and participant responsiveness; as described in chapter one). The overarching methods are described below (e.g. setting, sampling, eligibility criteria, recruitment and consent, scoring the degree of fidelity). However, due to the volume of different data collection and analysis strategies required to evaluate each element of the CFIF, the data collection and analysis sections are presented with their corresponding results section.

		ELEMENTS OF THE CFIF				Quality of delivery	Participant responsiveness
		Adherence					
		Coverage	Duration	Frequency	Content		
KEY COMPONENTS	StepByStep software	X	X				
	Therapy set-up	X	X	X	X	X	X
	Regular independent practice		X	X	X		X
	Supporting & monitoring use	X	X	X	X	X	

Table 4.1. Matrix to illustrate the elements of fidelity from the CFIF (Carroll et al, 2007; see chapter one, page 24) being evaluated for each of the key components

Setting

The data for this process evaluation was collected throughout the Big CACTUS trial at 20 NHS Trusts across the United Kingdom, co-ordinated by a central trial team at the University of Sheffield. The participants in the Big CACTUS study were community based. Data collection took place from October 2014 to September 2017.

Sampling

A total population sampling strategy was used for the majority of the process evaluation (exceptions described in subsequent data collection sections). This included not only the participants in the intervention arm of the Big CACTUS study (i.e. PWA), but also the therapist and the volunteer or assistant delivering the intervention.

Eligibility criteria

People with aphasia: The eligibility criteria were those utilised in the Big CACTUS trial (described in chapter one, page 38; Palmer et al, 2017) with one additional criterion excluding participants randomised to the usual care and attention control arms.

Speech and Language Therapists (SLTs): all SLTs (also referred to as therapists) involved in delivering the intervention in the Big CACTUS trial.

Volunteers/assistants: all volunteers and therapy assistants supporting PWA in the intervention arm of the Big CACTUS study.

Recruitment and consent

People with aphasia: as part of the trial PWA were recruited to the Big CACTUS study via NHS patient records, support groups and posters displayed in public spaces. A consent support tool (Palmer & Jayes, 2016) was used to determine the level of written and spoken understanding of the participant to determine how the study information would be presented and whether the PWA had capacity to provide informed consent or whether a close relative or friend should declare that they believe the PWA would want to participate (Mental Capacity Act; Office of Public Sector Information, 2005). More detail on the consent process can be found in the Big CACTUS trial protocol (Palmer et al, 2017).

Speech and Language Therapists: therapists were provided with an information sheet, consent form and a copy of the lead therapist quiz by email or post. The information sheet requested permission to use the data from the initial lead therapist quiz (originally collected to evaluate the training provided by the Big CACTUS trial team) and to collect two additional sets of quiz data.

Volunteers/assistants: volunteers and assistants were based at 20 NHS Trusts across the UK. The volunteers and assistants did not have direct contact with the central trial team. As such the principal investigators (PI) at each site were asked to distribute the information sheets and consent forms to volunteers and assistants.

Standard for comparison

In order to make a judgement about the extent to which the intervention was delivered as intended, it was necessary to have a standard for comparison. The StepByStep approach is described in a therapy manual written by the chief investigator of the Big CACTUS trial (Palmer, 2015), however some aspects (e.g. per protocol definition) are described in more detail in the Big CACTUS trial protocol (Palmer et al, 2017). Therefore, the protocol was used as the primary source for comparison. In particular, the per protocol definitions have been used where available, as these definitions provided minimum recommended frequencies and durations, unlike the therapy manual which details optimal delivery of the intervention.

Scoring the degree of fidelity

In order to make a value judgement about the extent to which each element of each intervention component was delivered as intended a 5-point scoring system was applied:

1. Very low (0-20%)
2. Low (21-40%)
3. Moderate (41-60%)
4. High (61-80%)
5. Very high (81-100%)

The scoring system could only be applied to components that have 1) a clear standard for comparison specified in the therapy manual or protocol, or 2) are scored out of a total amount where 100% is an indicator of strong performance. Where necessary, results have been transformed into percentages to allow the scoring system to be applied. Components that could not be scored have been described narratively as they still contributed important information about the process of delivering the intervention.

Ethical approval

The original ethical approval for the Big CACTUS trial (ISRCTN: 68798818) granted by Leeds West Research Ethics Committee (REC) and the Scottish A REC included some data collection that informed the process evaluation (activity logs, StepByStep access form and electronic key file data; all described in detail in subsequent sections). Ethical approval for

additional data collection for the process evaluation (lead therapist quiz, Working Alliance Inventory and participant responsiveness questions; also described in more detail in subsequent sections) was obtained by the author through approval of an amendment to the Big CACTUS trial protocol (version 4.0, 17 July 2015). For copies of the amendment approval letters see appendix F and G. All additional data collection was carried out by the author.

4.3 DATA COLLECTION, ANALYSIS AND FINDINGS

Adherence: data collection

The definition of adherence that informed the CFIF is whether an "intervention is being delivered as it was designed or written" (Mihalic, 2004). Adherence conceptualised within the CFIF incorporates frequency, duration, coverage and content (Carroll et al, 2007). Data collected to measure adherence to each key component is described in turn. Therapy set-up has been divided into therapist interaction with the PWA and therapist interaction with the volunteer/assistant due to the volume of data. Table 4.2 summarises how adherence to each intervention component was measured and analysed as well as detailing the standard for comparison from the Big CACTUS protocol (Palmer et al, 2017) or therapy manual (Palmer, 2015).

Intervention component		Element of fidelity measured	How was it measured	Measure completed by	How was it analysed	Standard for comparison (PP = Per Protocol description from Big CACTUS Protocol; P=Big CACTUS Protocol; TM = Therapy Manual)
StepByStep© software		Coverage and duration	'StepByStep access form' recorded dates of access and reasons for delayed start or periods with no access	SLT	Calculated proportion of participants provided with access, median duration of access and content analysis of qualitative comments	All of those allocated to the computer therapy arm were expected to receive the intervention (P) PP states a minimum "4 month period" of access to the StepByStep software taking into account holiday/illness
Therapy set-up: tailoring and personalisation	Overall	Duration	'Activity log: Therapist time with participant' and 'Activity log: therapist time with assistant/volunteer' recorded amount of time	SLT	Data from two activity logs combined to calculate the amount of time SLTs spent delivering the intervention overall	P states "approximately 4 hours therapy time in total"
	SLT supporting PWA	Coverage, frequency, duration and content	'Activity log: Therapist time with participant' recorded date, amount of time and type of activity carried out	SLT	Calculated proportion of participants receiving input, median frequency and duration of input and content described	P states "the intervention will be tailored, initiated and monitored by a SLT"
		Content	'Therapy planning form' showing what exercises were selected by SLT scored for completion	SLT	Calculated proportion of participants with complete therapy planning forms	TM states the SLT should "spend up to two hours checking that the individual is able to use the software and monitoring the appropriateness of the tailored exercises" P states "the intervention will be tailored, initiated and monitored by a SLT"
	SLT supporting volunteer/assistant	Coverage, frequency, duration and content	'Activity log: therapist time with assistant/volunteer' recorded date, amount of time and type of activity carried out	SLT	Calculated proportion of participants receiving input, median frequency and duration of input and content described	TM states "SLT should provide training" and "monitor the volunteer/assistant support"

Regular independent practice	Frequency and duration	Electronic key file from StepByStep software recorded date and time of practice	Electronic data capture exported by SLT	Calculated median frequency and duration of practice and described distribution	PP states practice should be carried out for a “minimum of 20 minutes 3 times a week at home on average” (i.e. 26 hours)
	Content	Electronic key file from StepByStep software recorded time spent on five different types of therapy exercise	Electronic data capture exported by SLT	Calculated median time spent on each type of therapy exercise and proportion of participants carrying out each type of exercise	TM states PWA should “work through the exercises”
Supporting and monitoring use	Coverage, frequency, duration and content	‘Activity log: Therapy assistant / volunteer time with participant’ recorded date, amount of time and type of activity carried out	SLT using information provided by volunteers/assistants on feedback form	Calculated proportion of participants receiving input, median frequency and duration of total input and different intervention activities	100% of those allocated to computer therapy were expected to receive the offer of support from a volunteer/assistant (P) PP states a minimum of 4 hours over 4 sessions Volunteer/assistant should: “observe and encourage use of computer exercises” [...] “encourage the use of new words in everyday situations through word games, conversation and discussions with family” (P)

Table 4.2. Table summarising methods of data collection, analysis and the standard for comparison for evaluating adherence to computer therapy

StepByStep© software

Whilst electronic data capture from the StepByStep software could demonstrate the extent to which the PWA adhered to the recommended dose, it could not take into account whether the PWA had the opportunity to practise (e.g. when access was provided by the therapist and when the computer/software was fully functional). Therapists completed a 'StepByStep access form (appendix H), documenting when the PWA was given access to the software and the reason for delay if more than two weeks after randomisation. Therapists were also asked to document any issues with access and the date access stopped and resumed.

Therapy set-up: tailoring and personalising

1. Overall therapy set-up

SLTs delivering the intervention completed activity logs detailing the time (duration) they spent supporting the PWA (appendix I) and the time spent supporting the volunteer/assistant (appendix J; more detail in section 2 and 3 below). The total amount of time (duration) was calculated by adding up the amount of time recorded on the two activity logs.

2. Therapy set-up: SLT supporting PWA

SLTs completed an activity log to record the time spent setting up and supporting the PWA to use the software. Data collected for each entry on the activity log included the date (frequency), activity type (content), time spent on each activity (duration) and whether the activity was conducted face-to-face, by telephone, email, video call, telehealth or therapist alone with software (appendix I). It is worth noting that the time spent setting up the software includes only the time tailoring the exercises to ensure the steps, prompts and cues match the therapy needs of the PWA. Selecting personally relevant vocabulary on the StepByStep software was not recorded on the activity log because it was conducted for all study participants before randomisation to the intervention group in the trial and activity logs were only completed once a participant was randomised to receive the computer intervention.

Intervention content was evaluated using the Therapy Planning Form (see appendix K for information about how the form was developed and appendix L for a copy of the form). As a neurorehabilitation intervention, *content* in this instance refers to the therapy intended to be delivered to the PWA. The content of the StepByStep approach is not merely the provision of the StepByStep software, but providing therapy exercises that

are personalised and tailored to the individual's specific needs by a SLT via the means of the StepByStep software. The Therapy Planning Form guided the therapists' selection of exercises based on the participant's language profile identified during assessment and required therapists to provide information about the sequence of therapy exercises selected and why (e.g. justification for tailoring). Completion of the Therapy Planning Form was used to indicate whether the therapy had been tailored to the needs of the individual. Completion was scored on a three point scale:

0 – no Therapy Planning Form available or 50% or less of Therapy Planning Form complete

1 – More than 50% of the Therapy Planning Form completed and some rationale provided

2 – 100% complete and some rationale provided for every discrete step (confrontation naming, using writing to cue naming, naming from grid and memory, using words in functional sentences)

3. Therapy set-up: SLT supporting volunteer/assistant

Another key component of the therapist's role was to support the volunteers/assistants supporting the PWA. A further activity log collected information about the therapist's interaction with the volunteer/assistant, including the date (frequency), activity type (content) and the time spent on each activity (duration) (appendix J). All activity logs were completed at site by the therapist after each contact and input directly onto the Big CACTUS database.

Regular independent practice

A key file in the StepByStep software is a digital file associated with one PWA, storing the exercises and vocabulary for practice as well as usage data including the date (frequency) and time (duration) of practice. Reliability of the key file data exported from StepByStep was considered. Reports from those using the software and brief testing demonstrated practice time was being recorded reliably (see appendix M). The key file records a wealth of data about the content of practice, such as which words have been practised, the prompts and cues the PWA has used and scores for therapy exercises that provide feedback. The specificity of much of this data makes it difficult to collate across multiple participants. However it was possible to collate information about the amount of time participants spent on the different types of therapy exercises (picture recognition, confrontation naming, using

writing to cue naming, naming in a grid and naming in functional sentences; for a detailed description of the exercises see chapter one, page 34).

Therapists exported key file data from the PWA's computer or tablet onto an encrypted memory stick at the end of the six months supported intervention period. For those participants who retained the software beyond the six-month intervention, additional practice data was collected by therapists approximately twelve months after randomisation (once participants' involvement in the study was complete). The memory stick was returned by post to the central trial team who securely shared the key files with the designers of the software, Steps Consulting Ltd, who converted the usage data into Microsoft Access format to facilitate analysis.

Supporting and monitoring use

Supporters were trained using the volunteer/assistant handbook (appendix A of the therapy manual; Palmer, 2015). As part of the intervention, volunteers/assistants completed a feedback form to facilitate the feedback cycle between the therapist and the volunteer/assistants supporting use. As a clinical tool the feedback form had the potential to contain sensitive personal information. Therefore, therapists were asked to collate the information from the feedback forms onto an activity log detailing the volunteer/assistants time with the PWA (appendix N). The activity log recorded the date (frequency), activity type (content) and time spent on each activity (duration). In addition, this log collected information about whether the PWA declined to receive input from a therapy assistant/volunteer (coverage) as it was an optional aspect of the intervention depending on the needs of the PWA.

Adherence: analysis

Quantitative data collected from the electronic key files, StepByStep access form, therapy planning forms and the three activity logs were analysed using descriptive statistics in SPSS v23 or Excel in order to calculate medians and ranges of the frequencies and durations of different intervention components and activities. In most instances the median was used as the measure of central tendency to limit the impact of skewness and outliers. Results were visually depicted using bar graphs. Comparisons between how the intervention was expected to be delivered (as described in the protocol and therapy manual) and how it was actually delivered within the Big CACTUS trial were scored and/or described narratively. See Table 4. for details of how each component was intended to be delivered.

Content analysis was applied to the qualitative free-text comments provided on the StepByStep access form. An inductive approach described by Elo & Kyngäs (2008) was adopted to analyse the manifest content employing three key stages: 1) open coding (writing notes in margin to describe content), 2) category creation (using notes to freely generate categories based on author interpretation) and 3) abstraction (creating codes and categories at different levels). The units of analysis were free-text comments provided by therapists in response to questions relating to delayed access to the computer therapy and periods when the computer therapy was not available. Responses to the two questions were analysed separately. Whilst this is a primarily qualitative approach to content analysis the number of times each high level category was identified within the data has been used to enable frequencies to be displayed visually. Three strategies were employed to increase the trustworthiness of the content analysis: 1) inclusion of quotations to increase credibility of selected categories and the relationships between the different categories, 2) the same question was asked of all therapists to increase dependability, and 3) the content analysis was situated within the wider process evaluation to provide as much contextual information as possible to increase transferability (Graneheim & Lundman, 2004).

Missing data

Data collected from the main trial database were exported in June 2017, at least three months after all participants had completed the intervention period of the trial, but three months prior to the end of trial data collection. The data was exported at this point due to the timescale of the PhD. For each data source, the number of participants with complete data is stated. As the purpose of this chapter is to describe the process of delivering the intervention, missing data was not assumed (as it was in the outcome focused main Big CACTUS HTA report; Palmer et al, in press), but was instead calculated from the number of participants for whom data had been received.

Adherence: findings

Adherence to the intervention's key components is described in detail before being summarised in table 4.7. As a process evaluation, the findings are presented in context and the discussion section will synthesise the two findings sections, consider the findings in light of the results of the Big CACTUS trial and draw conclusions.

StepByStep© software

The intervention arm of the Big CACTUS study comprised 97 participants. 100% of participants were provided with access to the StepByStep software (i.e. complete coverage) and therefore the opportunity to practise. The therapy manual recommends the software should be available for six months (183 days; Palmer, 2015), but the Big CACTUS per protocol definition states that the software should be available for a minimum period of four months (122 days; Palmer et al, 2017). Participants had access to the computer therapy for a median of 4.5 months (138 days; range 9-176 days) during the intervention period, which is 75% of the intended recommended duration, but meets the amount specified in the per protocol definition. 82% of participants received the therapy for the minimum recommended period of 4 months. None of the participants had access to the StepByStep software for the full six months during the intervention period as therapy set-up took place after randomisation.

Many participants retained access to the StepByStep software beyond the intervention period. Over this extended period 55% (n=53) of participants had access for six months and the median duration of access was 6.5 months (198 days; range 9-671 days). Wide variation in the total number of days of access recorded was anticipated due to the flexible nature of intervention delivery and differences in how data was recorded. The participant could withdraw from the trial at any point, which would result in premature access removal and/or key file export. Furthermore, the software was either provided on a computer loaned to the participant which was then retrieved six months after randomisation or the software was provided indefinitely on the participant's home computer. When provided on a home computer the access end date relates to the last time the SLT visited the participant to extract key file data (typically 12 months).

Trial documentation (StepByStep access form) only required details of delayed access if the delay was greater than two weeks, which implies this was the amount of time it was expected to take to tailor the therapy to the individual's specific language profile. Delay in accessing the software was greater than two weeks for 81% (n=79) of participants. The median delay between randomisation and accessing the computer therapy was 25 days (range 7-114 days). The reasons for delayed access were recorded as free text comments. Content analysis identified nine reasons for delay. See figure 4.2 for information about the number of times each reason was documented. Up to four reasons were documented per participant and the reasons were often dependent on one another.

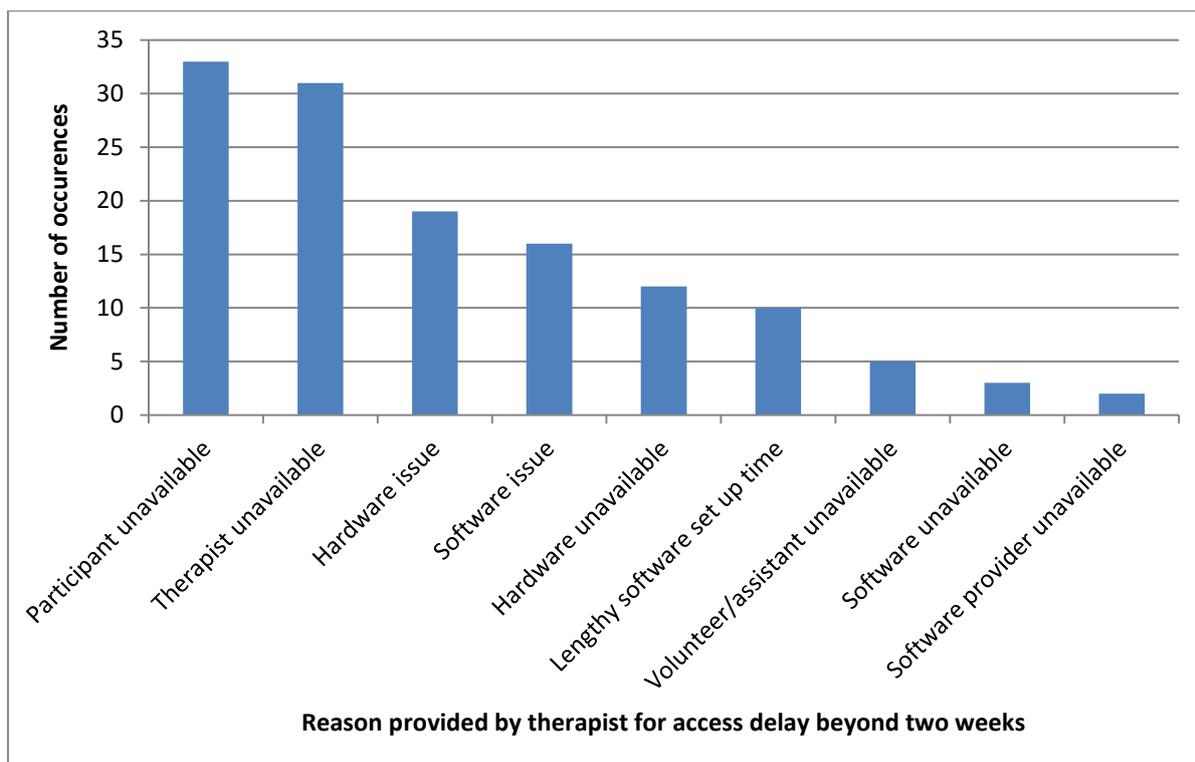


Figure 4.2. Graph illustrating the number of times each reason for delayed access occurred

The most common reasons for delayed access was the lack of availability of the participant (n=33) and the therapist (n=31), in both instances this was predominantly due to holiday and illness. Frequently it was a combination of both of their availability that resulted in access being delayed beyond two weeks.

“Therapist on Christmas holidays and then the client’s wife became ill.” (R02/42)

Issues with the hardware working (n=19) were more frequently reported than instances in which hardware was not available (n=12). Hardware issues comprised instances in which the participant’s computer/laptop did not function well enough for the software to be loaded onto it, difficulties logging onto NHS Trust owned devices (laptops/tablets) and problems with batteries and hard drives that required replacing. Instances in which the quality of the participant’s laptop prevented the software from being uploaded led to further delays when hardware was subsequently unavailable to loan to the participant.

“Initially problems uploading software as participant’s laptop was too old/slow so had to provide loan laptop at subsequent visit.” (R21/10)

Lack of availability of the hardware was most frequently caused by hold-ups relating to the IT department ordering or processing the devices.

“IT difficulties: IT unwilling to permit me to loan out Trust's laptop until they had made it sufficiently secure, due to their concerns re information governance.”
(R18/04)

Other reasons for lack of availability included waiting for a Trust owned laptop/tablet to be retrieved from another participant, hardware failure resulting in no device being available and the participants own device being sent away for repair.

Issues with the software were the fourth most common reason for delays in accessing the computer therapy. Most comments provided little detail regarding the specific nature of the problem. The more detailed comments described problems transferring the electronic key file from the therapist's laptop to the device the participant was going to use for practice, problems activating the StepByStep software licence on the device for participant use and issues with the voice recognition component not working. Several therapists commented on the need for input from the software providers and in some cases this was impeded by their limited availability.

“Delay was due to difficulty familiarising with software, problems with actual software functioning correctly, therapist illness and issues with speech recognition software needing support from steps consulting and IT dept.”
(R11/21)

In some cases the amount of time it took the therapist to set up the software for the individual was perceived to have caused the delay. The quotes below illustrate the tasks that were time consuming and the view shared by many therapists that set-up time was increased when the client had selected more personal vocabulary that was not already available on StepByStep due to the need to record additional prompts and cues.

“Length of time taken to setup therapy on computer including initial sound prompts and adding in sentences.” (R11/03)

“Additional time required to personalise software as client had selected lots of own personal vocabulary.” (R04/21)

On a small number of occasions, the lack of availability of the software, which had not yet been received from the software providers, delayed access to the computer therapy.

A period of inaccessibility after initial receipt of the computer therapy was experienced by 29% of participants (n=28) and lasted for a median of 15.5 days (range 2-80 days). Some participants were unable to access the software on more than one occasion with six participants having two periods of inaccessibility and one participant experiencing three

periods of inaccessibility. The reasons provided by therapists for periods of inaccessibility were categorised using content analysis. Unlike the reasons provided for a delay in setting up StepByStep, where there was typically more than one reason, access issues were typically attributed to a single cause. Figure 4.3 documents the number of times each reason was identified.

Technical problems with software and hardware accounted for 69% of the periods of inaccessibility. Where sufficient information was available this was categorised based on whether it was the hardware (n=12) or the software (n=11) preventing access. Further categorisation of the qualitative comments allowed this to be broken down into those problems that appeared to result from major malfunction of the software/hardware with limited human cause categorised as 'failure' of the hardware or software.

"Tablet given was faulty and had to wait for replacement" R07/08

Or an 'issue' with the software or hardware, when there was a difficulty with access due to a technical problem resulting from a human-computer interaction issue.

"Participant had wiped the programme off the computer. He then wanted to use the programme StepByStep only on a laptop. He did not want to borrow one. He purchased a laptop and the programme was reinstalled." R15/39

It is worth noting that all instances of software failure occurred in the earlier stages of the trial when the software was being regularly updated. Early in the trial two therapists incorrectly used the StepByStep access form to document participant holidays (n=3). The StepByStep access form was only intended to record access issues due to reasons beyond the participant's control.

Other reasons for disruption to access included a hospital or respite care admission (n=4), a significant health issue that prevented access (n=2), therapist removing access in order to make further adaptations to the software (n=1) and a participant whose family and work circumstances changed (n=1).

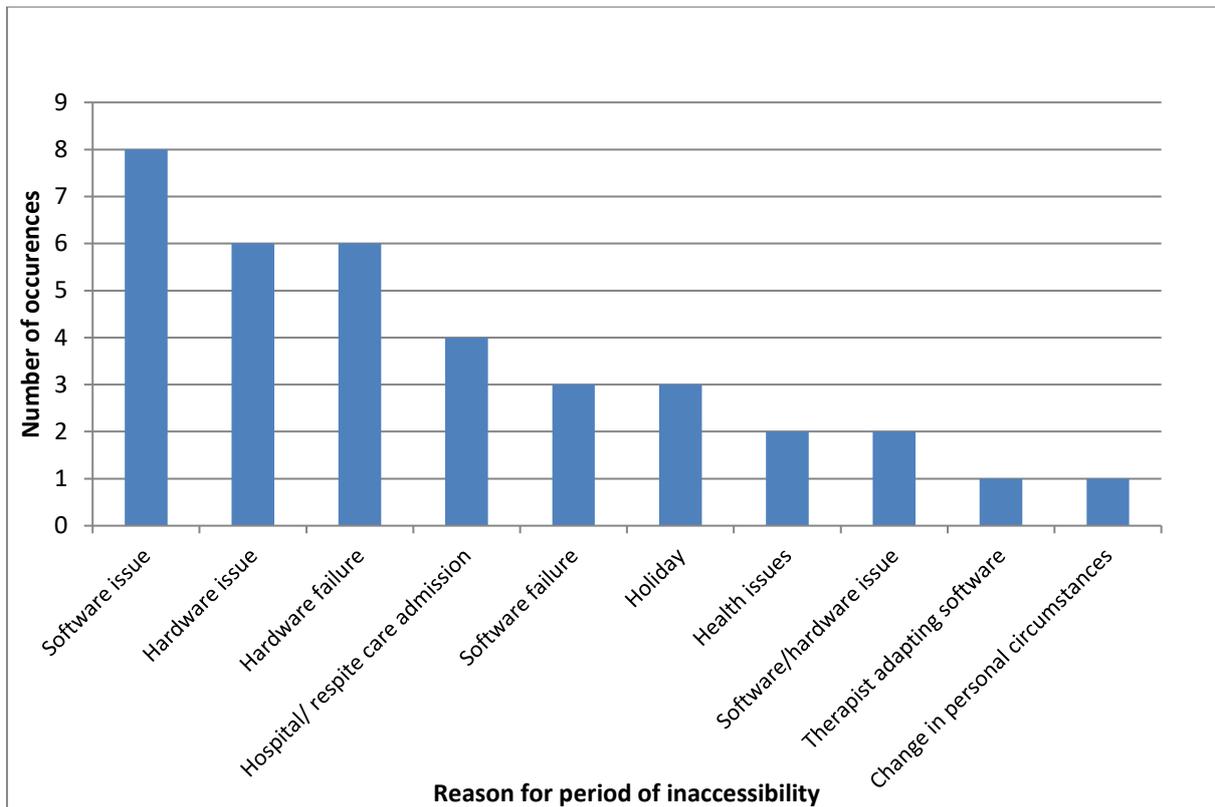


Figure 4.3. Graph illustrating the reasons for inaccessibility of StepByStep software during the intervention period

The reasons documented for delay and inaccessibility provide useful insights into the delivery of computer based interventions in ‘real world’ clinical practice in the NHS. However, complete coverage was achieved for the StepByStep software component and, despite delays, 82% of participants received the intervention for the minimum recommended duration of four months, thus indicating very high fidelity to the StepByStep software component.

Therapy set-up: tailoring and personalising

Overall duration of therapist input is presented first. Due to the level of detail collected on activity logs subsequent results will be divided into SLT supporting the PWA and SLT supporting the assistant/volunteer.

1. Overall therapy set-up

The protocol states “the intervention will be tailored, initiated and monitored by a SLT (approximately 4 hours therapy time in total)” (Palmer et al, 2017). Overall the therapists spent a median duration of 7 hours 35 minutes tailoring, personalising, supporting the

PWA and the assistants/volunteer and monitoring the intervention. Therapists spent more than the estimated four hours for 80% of participants (78/97). As there was no upper limit on the amount of time therapists spent delivering the intervention this demonstrates high fidelity to the duration of the therapy set-up component.

2. *Therapy set-up: SLT supporting PWA*

As described above, the protocol specified that “the intervention will be tailored, initiated and monitored by a SLT” (Palmer et al, 2017). An activity log detailing therapist time tailoring the software and supporting the participant was completed for all participants in the intervention arm indicating that all participants expected to receive the intervention had involvement from a therapist (i.e. complete coverage). The median amount of time spent setting up and supporting the participant over the seven months following randomisation³ was 5 hours 55 minutes (ranging from 30 minutes to 26 hours) and the median number of sessions was 4 (range 1-22). The ranges indicate a wide variation in the frequency and duration of sessions. This can be further broken down into the median amount of time spent interacting with the participants (face-to-face or via telephone or email) of 1 hour 45 minutes (range 0 minutes to 11 hours) over a median of 3 sessions (range 0-19) and the median amount of time the therapist spent alone setting up the StepByStep software of 4 hours (range 0 minutes to 18 hours 10 minutes) over a median of 1 session (range 0-11). Whilst a greater number of the therapy sessions were spent interacting with the participant, the therapists generally spent more of their time alone tailoring the StepByStep software.

The activity log allowed therapists to record three different activities they engaged in whilst delivering the StepByStep intervention (i.e. content). As seen in table 4.7 therapists spent time setting up StepByStep for all participants and the majority of sessions and time was spent setting up the StepByStep software. Fewer participants received technical support with less sessions and time spent on this activity, which is to be expected as not all participants would require this support, or it could have been provided by a volunteer/assistant. Monitoring participant progress was carried out for 47% of participants, with therapists spending a median of one session of 28 minutes on this activity (see table 4.3). This demonstrates moderate fidelity to ‘monitoring participant

³ *The decision to include therapist activity up to seven months post randomisation accounted for the fact that a final visit from a therapist to debrief the participant (if required) was expected to take place after the 6 month intervention period to ensure that full practice time data was collected on the electronic key file.*

progress', one aspect of the therapy set-up component, as the therapy manual states that the SLT should "spend up to two hours (spread over 1-3 sessions) checking that the individual is able to use the software and monitoring the appropriateness of the tailored exercises" (Palmer, 2015).

Activity type	Percentage of participants receiving each activity (n)	Median number of sessions conducted by therapists (range)	Median time across all sessions in hours and minutes (range)
Setting up StepByStep	100 (97)	2 (1-14)	4 hrs (5 mins–19hrs 45 mins)
Providing technical support to participant	76 (74)	2 (1-6)	1 hr (5 mins–6hrs 30 mins)
Monitoring participant progress	47 (46)	1 (1-18)	28 mins (5 mins–4hrs 15 mins)

Table 4.3. Content of intervention delivered by SLTs to PWA (n=97)

The therapy manual states that the "SLT should tailor computer exercises to the individual". The Therapy Planning Form provides evidence of the intervention having been tailored according to the individual's language profile. The Therapy Planning Forms were fully completed for 65% (n=63) of participants (i.e. rationale provided for every step), partially complete for 34% (n=33) of participants (i.e. more than 50% complete with some rationale provided) and one Therapy Planning Form was not available (1%; reason unknown). This indicates a high degree of adherence to the content of the tailoring component of the intervention. As described in the method, time spent personalising the vocabulary was not recorded on the activity log because it was carried out prior to randomisation. However, as all participants had a baseline personal vocabulary naming assessment complete coverage can be assumed. The degree to which the vocabulary was perceived to be personally relevant by PWA is described later (see page 142).

3. Therapy set-up: SLT supporting volunteer/assistant

Activity logs documenting SLT support for volunteers/assistants were completed for 92% of participants (n=89), indicating very high coverage of this aspect of the intervention. The median time therapists spent with each participant's volunteer/assistant was 1 hour 40 minutes (range 20 minutes – 8 hours 35 minutes) across a median of 4 sessions

(range 1-13). The activity type (i.e. content of the intervention) shown in table 4.4 demonstrates that the majority of assistants/volunteers supporting participants were provided with training (93%) and on-going support (84%) from the therapists. Training was typically delivered once for one hour, and the median number of support sessions was two lasting a median of 30 minutes. Approximately half of the assistants or volunteers supporting the participants had their feedback forms monitored (52%) by the SLT. The therapy manual states that the assistant/volunteer should complete a feedback form and return it to the SLT each time they see the participant (approximately 6-12 sessions) and “the SLT should use this to monitor the volunteer/assistant support and the progress of the patient”. This suggests that two-way communication between the SLT and the volunteer/assistant was not occurring for approximately half of participants, indicating moderate fidelity to this activity (i.e. content). For those assistants/volunteers whose feedback forms were monitored this occurred for a median of 20 minutes over 3 sessions.

Activity type	Percentage of participants (n) whose volunteer or assistant received each activity	Median number of sessions conducted by therapists (range)	Median time across all sessions in hours and minutes (range)
SLT training assistants/ volunteers	93 (83)	1 (1-4)	1 hr (15 mins – 4 hours)
SLT supporting assistants/ volunteers	84 (75)	2 (1-7)	30 mins (5 mins – 3 hours)
SLT providing technical support to assistants/ volunteers	49 (44)	1 (1-5)	20 mins (5 mins – 1 hour 45 mins)
SLT monitoring feedback forms from assistants/ volunteers	52 (46)	3 (1-7)	20 mins (5 mins – 1 hour 40 mins)

Table 4.4. Content of intervention delivered by SLTs to volunteers or assistants (recorded per participant; n=89)

Person with aphasia carrying out regular independent practice

Usable key file data was received for 91% (n=88) of participants randomised to the intervention arm of the Big CACTUS trial. Reasons for the nine missing key files included site processing error (n=5), StepByStep key file corruption (n=2), hardware failure (n=1) and loss of contact with participant (n=1). Participants with no key file data are not included in the analysis for this section. Of the 88 key files received, three included only partial data (e.g. no record of practice for 50% or more of total intervention period) due to technical issues with

software or hardware. Partial data was included and has not been imputed as patterns of practice might vary over time. This will have resulted in a conservative estimate of practice for three participants.

In the six month intervention period participant’s median duration of practice was 25 hours 57 minutes (range 0 minutes – 103 hours 44 minutes). The distribution of practice time across participants shown in figure 4.4 illustrates the variability in the amount of time participants chose to practise. However, there is a downward trend with fewer participants practising for longer durations particularly beyond 70 hours. 18% of participants practised for five hours or less, but within that category it is worth noting that 61% of those participants practised for less than two hours, an amount of time we would expect to have been carried out with a volunteer/assistant, thus indicating they did not engage in regular independent practice.

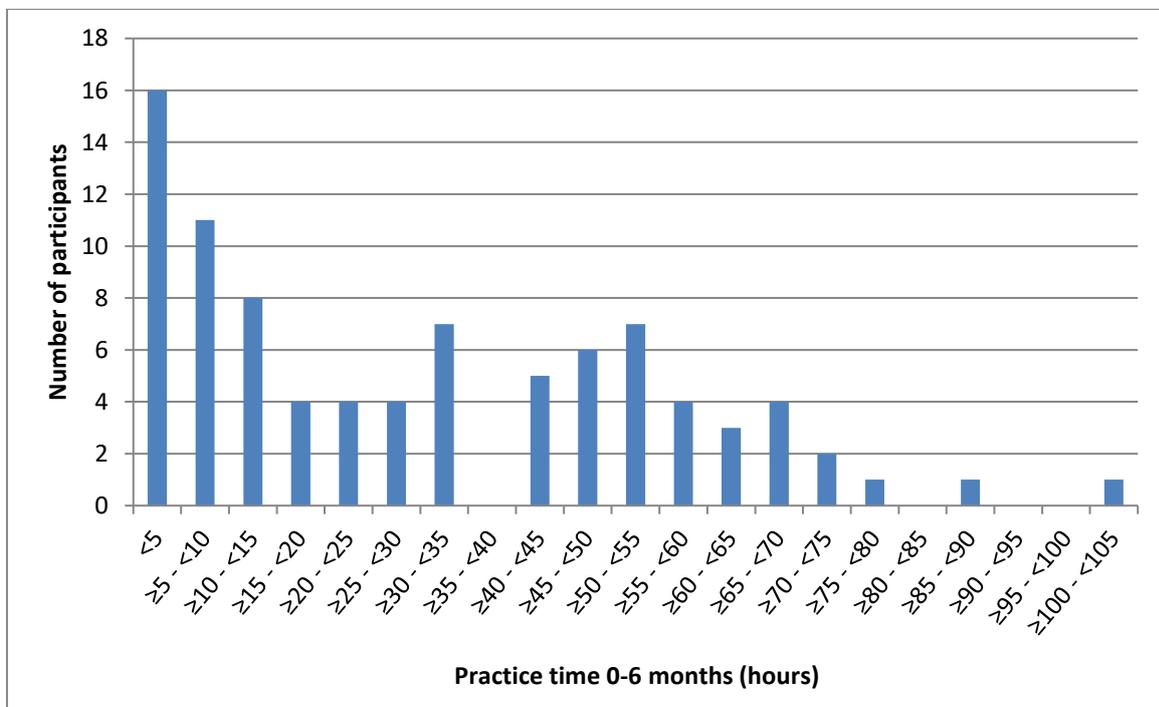


Figure 4.4. Total practice time in six month supported intervention period (n=88)

The median number of days with practice recorded was 63 (range 0-176 days). The therapy manual and protocol refer to the number of practice sessions in terms of the frequency (days of practice per week), rather than the overall number of practice sessions. As such, the mean number of days with practice per week was calculated by dividing the total number of days when practice occurred by the total number of days the intervention was available to the participant during the intervention period and multiplying the figure by seven. This

resulted in a median of three practice sessions per week on average over the intervention period. Figure 4.5 shows the number of days participants practised per week, which demonstrates the wide variability in how often participants chose to practise the computer therapy, with a slight downward trend as the number of days per week increases. 50% of participants practised on average three times per week or more.

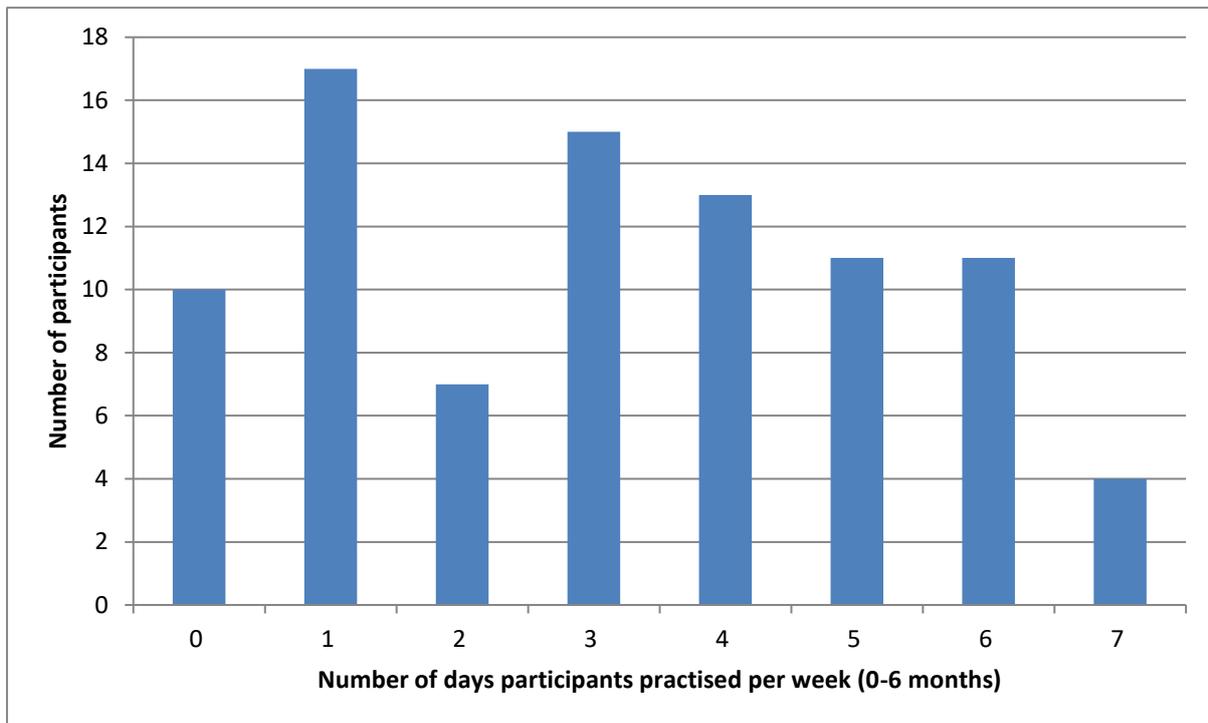


Figure 4.5. Bar chart showing the average number of days participants (n=88) practised per week during the six month intervention period

The therapy manual recommends 20-30 minutes of computer therapy practice each day over a six month period (Palmer, 2015). Using the lower recommended amount of 20 minutes this equates to a total of 61 hours over six months. Only 14% of participants practised for more than 61 hours and only 1% of participants practised every day the therapy was available for six months. The therapy manual does however acknowledge that the overall amount of practice will be reduced by periods of holiday and illness. As such, the Big CACTUS trial protocol stated that a minimum of 20 minutes practice three times a week for six months would be considered per protocol (Palmer et al, 2017), which equates to a total of 26 hours. When comparing to this per protocol definition, 50% of all participants practised for the recommended amount of time or more (n= 44) and the median duration of practice (25 hours 57 minutes) was similar to the recommended minimum practice time, indicating a

moderate degree of fidelity. Similarly the median frequency of three practice sessions per week was the same as the recommended minimum frequency and 50% of participants practised three times per week (n=44), indicating a moderate degree of fidelity.

The StepByStep key file also records practice time for the five different types of therapy exercises (also known as steps) within the StepByStep therapy software. The median times (hours) are presented in table 4.5. The exercise participants spent the most time practising was ‘using writing to cue naming’ in which a picture is presented and participants have to spell the word using a keyboard. This therapy exercise would more commonly be used to practise and improve writing (an outcome that was not measured as part of the Big CACTUS trial). However the task is called ‘using writing to cue naming’ as it is intended that “once the patient knows what the word is he/she can press the microphone button, record the spoken word and receive feedback” (Palmer, 2015). However, the extent to which this function was actually used is unknown, but we do know from free text comments on the therapy planning form that due to issues with the voice recognition some therapists hid this function. Of the three unambiguous naming exercises participants spent the most time on the confrontation naming exercises, followed by naming words in functional sentences, with the least time spent naming words from a grid. The combined median amount of practice across the three unambiguous naming exercises was less than the time spent using writing to cue naming. The picture recognition exercise was the fourth least used exercise overall. One might have expected participants to have spent less time on this exercise, as compared to the other exercises, as it “is designed for familiarisation of the vocabulary by using simple matching tasks” (Palmer, 2015).

Exercise type	Median time across all sessions in hours and minutes (range)	Number of participants using exercise (percentage)
Picture recognition	1hr 31mins (4 mins - 42 hrs 47 mins)	83 (97%)
Confrontation naming	5 hrs 32 mins (1 min - 56 hrs 1 min)	85 (99%)
Using writing to cue naming	9 hrs 7 mins (1 min - 82 hrs 40 min)	78 (91%)
Naming from grid	1 hr 3 mins (1 min – 20 hr 40 mins)	74 (86%)
Naming words in functional sentences	1 hr 38 mins (3 mins – 33 hr 22 mins)	76 (88%)

Table 4.5. Therapy content: time participants spent practising different types of the therapy exercises (n=86)

Supporting and monitoring use

Activity logs were completed by the volunteers/assistants about their interactions with the PWA for 89% of intervention arm participants (n=86), indicating very high coverage of this component. One PWA declined support from a volunteer/assistant. Of the 86 participants with completed activity logs, a median of 5 sessions (range 1-12) took place between the volunteer/assistant and the PWA over a median of 4 hours and 15 minutes (range 20 minutes to 8 hours 45 minutes). The therapy manual recommended that participants should receive six hours of input, which was achieved for 17% of participants, over at least six sessions, which was achieved for 43% of participants. However, the per protocol definition states a minimum of four hours, which was achieved for 55% of participants (indicating moderate fidelity to duration), over at least four sessions, which was achieved for 77% of participants (indicating high fidelity to frequency).

The type of activity (i.e. content) the volunteer/assistant engaged in with the PWA is shown in table 4.6. The majority of participants, for whom an activity log was completed, received encouragement and motivation to use the computer therapy from the volunteer/assistant (99%), which was delivered for a median of 1 hour 25 minutes across 4 sessions. Other activities were carried out with only 90% of participants, whilst this might have been due to lack of need in the case of setting up or adjusting the computer or microphone (87%) or assistance with using the software (90%), encouraging the use of new words through practising them in conversation had the potential to be useful for all participants, but was carried out with 85% of participants. Also the median amount of time spent having conversations to practise using the words in everyday life was 45 minutes. This was the component of the intervention aimed at aiding generalisation of naming.

Activity type	Percentage of participants receiving each activity (n)	Median number of sessions conducted by assistants/ volunteers (range)	Median time across all sessions in hours and minutes (range)
Setting up/ adjusting computer or microphone	87 (75)	3 (1-9)	40 mins (3 mins to 3 hrs 5 mins)
Encouraging/ motivating use of the computer therapy	99 (85)	4 (1-10)	1 hr 25 mins (10 mins – 5 hrs 50 mins)
Assistance with using software	90 (77)	3 (1-9)	1 hr (5 mins – 5 hrs 2 mins)
Conversations to practise using the words	85 (73)	4 (1-9)	45 mins (5 mins – 2 hrs 35 mins)

Table 4.6. Content of intervention delivered by volunteers or assistants to the PWA (n=86)

Intervention component		Aspect of adherence	Actual delivery	Standard for comparison (PP = Per Protocol description from Big CACTUS Protocol; P=Big CACTUS Protocol; TM = Therapy Manual)	Degree of fidelity
StepByStep© software		Coverage	100% of participants received computer therapy	All of those allocated to the computer therapy arm were expected to receive the intervention (P)	Very high
		Duration	82% of participants had access for 4 months	PP states a minimum “4 month period” of access to the StepByStep software taking into account holiday/illness	Very high
Therapy set-up: tailoring and personalisation	Overall	Duration	80% of participants received the estimated four hours input from a SLT	P states “approximately 4 hours therapy time in total”	High
	SLT supporting PWA	Coverage	100% of participants received SLT input for therapy set-up	P states “the intervention will be tailored, initiated and monitored by a SLT”	Very high
		Duration	Median amount of SLT time 6 hours (range 0.5-26 hours)		N/A*
		Frequency	Median number of SLT sessions 4 (range 1-22)		N/A*
	Content		47% received monitoring of their progress	TM states the SLT should “spend up to two hours checking that the individual is able to use the software and monitoring the appropriateness of the tailored exercises”	Moderate
			65% of participants had complete documentation regarding the tailoring of exercises to the PWA’s specific language profile	P states “the intervention will be tailored, initiated and monitored by a SLT”	High
	SLT supporting volunteer/assistant	Coverage	93% of participants had volunteers/assistants who had received input from an SLT	TM states “SLT should provide training” and “monitor the volunteer/assistant support”	Very high
		Duration	Median amount of time 1.7 hours (range 0.3 – 8.6 hours)		N/A*

	Frequency	Median of 4 sessions		N/A*
	Content	92% of participants had volunteers/assistants who had received training 52% of participants had volunteers/assistants who had received monitoring of the support they were providing		Very high Moderate
Regular independent practice	Duration	50% of participants practised for 26 hours or more	PP states practice should be carried out for a “minimum of 20 minutes 3 times a week at home on average” (i.e. 26 hours)	Moderate
	Frequency	50% of participants practised on average three times per week or more		Moderate
	Content	Median time on each exercise: picture recognition 1.5 hours, confrontation naming 5.5 hours, using writing to cue naming 9.1 hours, naming from grid 1.1 hours, naming words in functional sentences 1.6 hours	TM states PWA should “work through the exercises”	N/A
Supporting and monitoring use	Coverage	89% of participants received support (1% declined input, 10% had no documentation relating to support)	100% of those allocated to receive computer therapy were expected to receive the offer of support from a volunteer/assistant (P)	Very high
	Duration	55% of participants received the recommended amount of support	PP states a minimum of 4 hours over 4 sessions	Moderate
	Frequency	77% of participants received the recommended number of sessions		High
	Content	99% of participants received encouragement/motivation to use the computer therapy 85% engaged in conversations to practise using their words	Volunteer/assistant should: “observe and encourage use of computer exercises” [...] “encourage the use of new words in everyday situations through word games, conversation and discussions with family” (P)	Very high Very high

Table 4.7. Summary of fidelity assesment of each aspect of adherence

* No fidelity score assigned due to lack of specific guidance regarding intended delivery

Summary of adherence results

The results of the evaluation of adherence are summarised in table 4.7. The degree of fidelity of each component has been assessed on a five point scale (very low to very high) based on the percentage of participants who received the intervention as intended by the therapy manual or protocol. Translating the scale into a score (1-5; 1=very low adherence) allows a summary score to be created for each component of the intervention and each element of adherence (see table 4.8).

		ADHERENCE				
		Coverage	Duration	Frequency	Content	MEAN
KEY COMPONENTS OF THE INTERVENTION	StepByStep software	5	5	-	-	5
	Therapy set-up (overall*)	5	4	-	3.8	4.26
	Regular independent practice	-	3	3	-	3
	Supporting and monitoring use	5	3	4	5	4.25
MEAN		5	3.75	3.5	4.4	

Table 4.8. Summary scores for adherence

* The overall score was achieved by averaging scores for coverage and content of SLT supporting participant and SLT supporting volunteer/assistant

Based on the summary scores in table 4.8, moderate fidelity, or better, was achieved for all components of the intervention. The StepByStep software was delivered with a very high degree of fidelity (see table 4.8). Therapy set-up and supporting and monitoring use were both delivered with a high degree of fidelity. As a self-managed intervention the participant chose how much independent practice to carry out. Regular independent practice was carried out with moderate fidelity. As well as considering how each of the components of the intervention were delivered and received it is also possible to see patterns in the different aspects of adherence. All components scored very highly for coverage indicating that the vast majority of participants received, at least to some extent, the key components of the therapy. Adherence to content only had a standard for comparison for two of the

components, so whilst it scored highly overall it is important that the nuances in delivery of content described above are taken into account in the overall discussion. Adherence to the intended frequency and duration of the various components scored moderately. Frequency and duration equate to the dose of therapy. Recent research indicates that sufficient dose of treatment is required in order to make clinical gains in aphasia therapy (Doogan et al, 2018). While the true optimal dose of this therapy is not known, the dose recommended in the therapy manual and protocol was based on the chief investigators clinical experience and the mean dose achieved in the pilot study (Palmer et al, 2012). As such, moderate fidelity for these elements might have impacted upon the clinical gains made by participants within the study.

Throughout the results section each component has been measured and described in isolation, but just as the components of a complex intervention are highly interconnected, as is adherence to these components. An example is presented in Figure 4.6 demonstrating how high adherence to some components might have resulted in lower adherence to other components. The lengthy therapist set-up time, which lasted a median of 7.6 hours compared to the estimated four hours (based on pilot CACTUS trial data using version 4.5 of the StepByStep software), contributed to access being delayed for more than 2 weeks for 81% of participants, which in turn might have reduced the frequency and duration of independent practice and the support and monitoring provided by the volunteer/assistant.

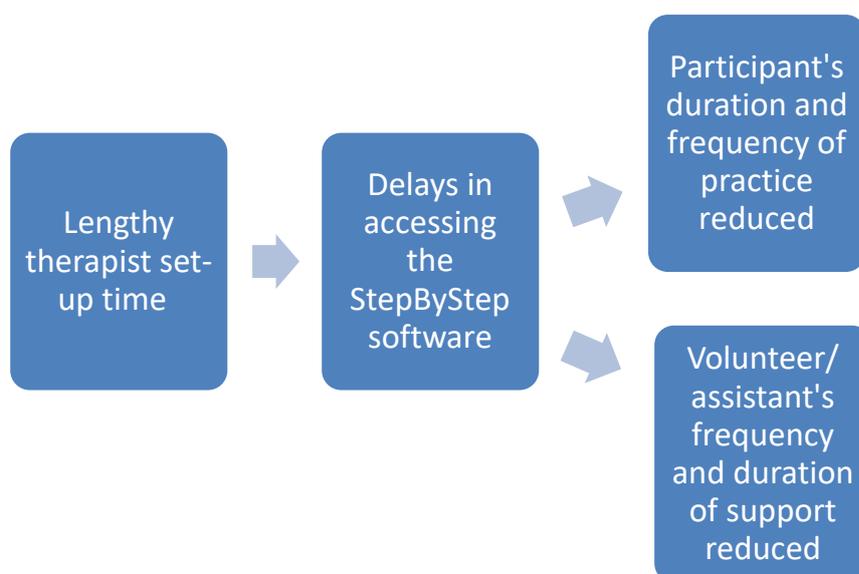


Figure 4.6. Example of interdependency of adherence to different components of the StepByStep approach

It is worth noting that the summary scores in table 4.8 must be interpreted with caution because each component of the intervention was not necessarily of equal importance and not all elements could be scored for each component. It is also worth noting that trial procedures have impacted on how the results have been calculated. The start of the intervention period in the trial was the date of randomisation, however in practice this would be calculated from the point at which the SLT starts tailoring the software for the PWA. This would have potentially altered the findings in terms of the duration of time the StepByStep software was available to the participant and the amount of independent practice recorded, as practice data was capped at six months post-randomisation for this analysis.

Moderators of adherence: data collection

Intervention components related to quality of delivery and participant responsiveness were evaluated through measuring and describing therapist qualification, experience, training and learning effects, how the therapy was tailored, the relationship between the PWA and the volunteer/assistant, as well as participants' level of motivation, perceived ease of use of the software and degree of personalisation of the vocabulary used in the therapy exercises. Data collection methods for each component are described in turn and summarised in table 4.9.

Quality of delivery: Therapist qualification, experience, training and learning effects

Therapist qualification, experience and training was systematically recorded by the central Big CACTUS team through documenting the therapist's Agenda for Change (AfC) band and recording attendance at training sessions. Agenda for change band is used as a proxy for therapist experience. The majority of qualified SLTs are employed on bands 6 and 7, while newly qualified SLTs typically start on band 5 (Rossiter, 2006).

Attending training does not necessarily equate to having learnt the knowledge or skills covered in the training. A recent review of process evaluations conducted alongside RCTs highlighted the importance of monitoring the learning effects of staff delivering the intervention (Masterson-Algar et al, 2016). In order to evaluate the therapists learning over time, the therapists were invited to complete the 'lead therapist quiz' at three time points. See appendix O for information about the development of the lead therapist quiz and appendix P for a copy of the quiz. A delay was often experienced between SLTs receiving training and starting to deliver the intervention due to administrative hold-ups and first participants recruited being randomised to attention control or usual care. As such the initial time-point was five months after each SLT randomised their first participant to the trial with follow-ups sent out 10 and 15 months after the first participant was randomised at their site. The lead therapist quiz comprised eleven questions including: "What information should you collect to decide how StepByStep should be tailored?" and "What would you advise the volunteer/assistant to do if they fed back to you that the participant insists on keeping on practising the easier levels because they can get them all correct?". All questions required free text answers. The questions were generated by trial team members who provided training on the relevant component of the intervention.

Consent to use data from the quiz was sought at the 10 month time point. An information sheet and consent form was sent by post from the author, retrospectively seeking consent to use data from the 5 month time point (the quiz was initially carried out by the trial team to

evaluate the training) and inviting therapists to complete the lead therapist quiz at the 10 and 15 month time points. Therapists received two reminders to complete the quiz. The author scored the quiz according to a list of pre-determined answers provided by the member of the trial team who wrote the question and consulted them if there was any uncertainty regarding the score.

Quality of delivery: How the therapy was tailored

The Therapy Planning Form guided the therapists' selection of exercises based on the participant's language profile identified during assessment and provided information about the sequence of therapy exercises selected and why (e.g. justification for tailoring). Data collection for the Therapy Planning Form is described above on page 109 in relation to evaluating adherence to intervention content, however the same tool has also been used to provide insights about the quality of delivery of the intervention.

An SLT with expertise in the StepByStep approach studied a sample of the Therapy Planning Forms. The sample was stratified by site. A Therapy Planning Form was selected at random (forms reversed and selected at random by a colleague) from each site participating in the study resulting in sample size of 21, approximately 20% of the total number of Therapy Planning Forms.

The Therapy Planning Form was scored by the expert SLT who wrote the therapy manual based on whether they understood why the steps had been tailored in the way they had based on the summary of assessment results documented on the second page of the Therapy Planning Form. Each Therapy Planning Form was scored on a 3 point scale:

- 0 – Not clear why steps have been tailored in this way
- 1 – Some understanding of why steps have been tailored in this way
- 2 – Comprehensive understanding of why steps have been tailored in this way

As well as providing a score the expert also provided free text comments.

The final page of the Therapy Planning Form comprised a table for therapists delivering the intervention to document any adaptations made to the software after it was originally provided. It was anticipated that changes would need to be made to therapy set-up during the intervention period based on feedback from the volunteer, assistant or participant themselves. This was highlighted as an important aspect of therapy delivery by key informants in study two (see StepByStep diagram, page 81). Data collected included the number of adaptations, date the adaptations were made and free text comments about how the exercises were adapted in response to the PWA's performance.

Quality of delivery: Relationship between the PWA and the volunteer/assistant

As the main source of on-going support during the intervention the volunteers/therapy assistants' relationship with the participant was identified as a key component of the intervention in the interviews in chapter three (see page 94). Many disciplines recognise the importance of the relationship between those providing and receiving care and the impact this can have on the quality of intervention delivery and thus the effectiveness of behavioural interventions (Bellg et al, 2004). Working alliance scales measure the relationship between therapist and client. The concept of the working alliance is based on a collaborative relationship between client and therapist comprised of (1) client and therapist agreement on goals, (2) agreement on the tasks needed to achieve these goals, and (3) the development of a bond of mutual trust, confidence and personal liking (Bordin, 1979). The quality of the working alliance has been found to be positively associated with successful therapy outcomes in multiple contexts (Horvath & Symonds, 1991).

Collecting data directly from the participants with aphasia would have been the most reliable way of measuring alliance, but due to the complexity of the language used in validated alliance scales they were not thought to be suitable for use with an aphasic population. As such the volunteers/therapy assistants were asked to complete the 'Working Alliance Inventory – Short Revised – Therapist' version (WAI-SRT; Hatcher & Gillaspay, 2006) after the three month visit to the participant.

The WAI-SRT is a measure of the therapy provider's perception of the quality of the working alliance with the patient (Hatcher and Gillaspay, 2006). The inventory comprises 10 items, with four corresponding to quality of therapeutic bond (e.g. '_____ and I respect each other') and three items corresponding to agreement on tasks (e.g. 'We agree on what is important for _____ to work on'), and agreement on goals (e.g. 'We are working on mutually agreed upon goals'). A Likert scale ranging from 1 ('seldom') to 5 ('always') is used to score alliance with a high score indicating strong working alliance. The WAI-SRT has been validated against the original 36 item Working Alliance Inventory (Horvath & Greenberg, 1989).

The lead therapist provided the volunteer/therapy assistant with a participant information sheet and consent form before asking them to complete the WAI-SRT. The volunteer/therapy assistant had the option of returning the completed WAI-SRT via the lead therapist or directly to the research team to ensure anonymity. The author calculated the score for each returned WAI-SRT using the weighted scoring system (Hatcher & Gillaspay, 2006).

Participant responsiveness: Motivation, ease of use and personalisation

Key informants in study two identified three moderators of adherence relating to participant responsiveness: how motivated the participants were to practise the therapy exercises, how easy the participants found the software to use and the extent to which the PWA felt the vocabulary they were practising had been personalised. Qualitative exploration of these factors took place as part of the interviews with a small sample of low and high adhering participants (see chapter five). In order to measure these concepts more widely amongst participants, a self-report style measure was developed. Due to the written and verbal comprehension impairments caused by aphasia it was necessary to ensure the language and presentation were aphasia-friendly. In collaboration with stroke survivors and carers in the Big CACTUS patient and carer advisory group, three visual analogue scales were developed using large font, emboldening of words and pictures to represent the concepts (see appendix Q for details of the development process and appendix R for a copy of the questions). For the visual analogue scale relating to motivation participants were asked to circle how they felt on a 10-point scale with 1 being very motivated and 10 not motivated. Similarly, a 10-point scale was used for the ease of use scale, ranging from 1 very easy to 10 not easy at all. The third visual analogue scale about the level of personalisation of vocabulary was scored on a 5-point scale ranging from 'all' to 'none' of the words having been personalised. Despite the accessible format, reading the questions still required a certain level of written understanding. As such the questions were only sent to participants who had a carer involved in the study or those who demonstrated written understanding of three key words or more on the Consent Support Tool (Palmer & Jayes, 2016). The three additional questions were sent directly to intervention arm participants three months into the intervention period alongside a pre-paid envelope for return.

Intervention component	What was measured	How was it measured	Measure completed by	How was it analysed	What was the standard for comparison (Therapy manual = TM; Big CACTUS protocol = P)
StepByStep software	Ease of use	10-point VAS (1= very easy)	PWA	Median and range of scores calculated	N/A
Therapy set-up: tailoring and personalisation	Therapist qualification, experience, training and learning effects	Attendance at training and AfC band recorded as a proxy measure of experience	Trial team	Proportion of participants with requisite qualification, experience and training calculated	“The SLT providing this intervention should hold a speech and language therapy qualification from an institution recognised by the Royal College of Speech and Language Therapists. The therapist should have experience of providing therapy to PWA as a consequence of stroke. They should have received training on how to use the software and provide the StepByStep intervention.” (TM)
		‘Lead therapist quiz’ completed 5,10 and 15 months after randomisation of first participant	SLT	Median scores calculated, plotted scores at different time points, Friedman test explored differences in scores across time	
	How therapy was tailored	‘Therapy planning form’ assessed for sense of rationale by StepByStep approach expert	SLT	Quality of tailoring scored on 3 point scale	“Qualified SLT assessment of patient’s language profile to tailor computer exercises using the StepByStep© software so that they target the specific language deficit identified.” (TM)
		Number of adaptations and reasons for them following initial therapy set up	SLT	Number of adaptations counted, content analysis of free text comments, count of reasons for adaptations	No specific standard, but “changes to the exercise set up and additional vocabulary can be made by the volunteer/assistant under the guidance of the therapist.” (TM)
Personalisation	5-point VAS (all – none)	PWA	Median and range of scores calculated	“Creation of exercises using target words of personal relevance to the patient.” (TM)	

Regular independent practice	Ease of use	10-point VAS (1= very easy)	PWA	Median and range of scores calculated	N/A
	Motivation	10-point VAS (1= very motivated)	PWA	Median and range of scores calculated	TM states that the software is designed and the volunteers/assistants are there to help “encourage motivation for self-managed practice”
Supporting and monitoring use	Relationship between the PWA and the volunteer/assistant	WAI-SRT completed half way through the intervention period	Volunteer/assistant	Mean WAI-SRT score calculated as well as mean score for the three sub-scales	“The volunteer/assistant should [...] encourage use of computer exercises; check results and discuss difficulties; assist patient to move on to harder tasks [...]; encourage the use of new words in everyday situations through word games, conversation and discussions with family” (TM)

Table 4.9. Measures to evaluate the factors moderating adherence

Moderators of adherence: analysis

Specific analysis for each component is described in table 4.9. Quantitative data was analysed using descriptive statistics in SPSS v23 or Excel. Free text comments used to describe adaptations were analysed using content analysis as described above in the adherence analysis section (see page 111).

Moderators of adherence: findings

Quality of delivery: Therapist qualification, experience, training and learning effects

As specified in the therapy manual, all individuals assessing the PWA, tailoring and personalising the therapy were qualified SLTs, indicating very high fidelity. The median AfC band was band 7, ranging from band 6 to band 8b. The range of bands indicates that there were SLTs with a variety of levels of experience involved in delivering the intervention. The absence of band 5 therapists demonstrates that newly qualified SLTs were not involved in delivering the intervention.

As recommended in the therapy manual, all SLTs delivering the StepByStep approach to computer therapy attended a one-day training session delivered by the central Big CACTUS trial team indicating very high fidelity. Training on delivering the intervention included providing an introduction to the main components of the intervention, detailed training on how the software works and how you might personalise and tailor the intervention depending on the needs of the PWA (this element of the training was designed through consultation with the software designers/providers to emulate the training they provide to people who purchase the software) and training on how to train and work with volunteers/assistants in order to deliver the intervention.

Therapists at all 21 sites completed the initial lead therapist quiz at time point 1 (5 months after the first randomisation at each site). The median score was 10 (range 7-13) out of 15. As this was the only time-point at which all therapists completed the quiz this data has been used to derive a fidelity score. A median score of 10/15 equates to 67% and can thus be interpreted as indicative of a high quality of delivery. The quiz was completed by 17 therapists at time point 2 (5 months later) and the median score was 11 (range 7-14). The quiz was completed by 17 therapists at time point 3 (another 5 months later) and the median score was 13 (range 7-13). Thus demonstrating a slight increase in therapist knowledge about the intervention as they spent more time delivering it. Only 15 therapists completed the quiz at all three time points so the results are not directly comparable.

One of the questions on the lead therapist quiz asked therapists to identify the key components of the intervention. The components of the intervention were covered in the training provided to all therapists. The responses to this question from the first time point have been counted. Of the 21 SLTs that completed the form 17 described the regular independent practice component, 16 described at least one aspect of therapy set-up (personalisation of vocabulary or tailoring of the exercises), 4 described the StepByStep software as a whole, and only 1 described volunteer/assistant support as being a key component. In addition 10 SLTs described specific features of the software, such as the voice recognition, graded cueing, word-finding exercises and immediate feedback. Some of the participants that had done this appeared to view the features or exercises of the StepByStep software as the components of the StepByStep approach, as demonstrated in the quote from one SLT's quiz:

- “1. Matching picture to spoken/written word*
- 2. word production with cueing in response to picture stimulus*
- 3. sentence production in response to cueing” (LT05)*

Quality of delivery: How therapy was tailored

The StepByStep approach expert had a comprehensive understanding of why the steps had been tailored in this way, based on the information in the summary of assessment results, for 66% (n=14) of Therapy Planning Forms, some understanding of why steps had been tailored in this way for 24% (n=5) and was not clear why steps had been tailored as they had been for 10% of the sample (n=2). The presence of a sound rationale for tailoring for 66% of the Therapy Planning Forms evaluated indicates high fidelity for how the therapy was tailored to the individual's needs.

The StepByStep expert wrote down her observations as well as scoring the Therapy Planning Form. Observations were provided for all therapy planning forms not receiving a score of 2. One of the Therapy Planning Forms scored 0 because no tailoring of the exercises was documented. The other lacked assessment results and the tailoring did not follow the theory of errorless learning (see chapter one, page 30), which underpins the design and delivery of the StepByStep software. For forms scoring 1 the observations indicated that in three instances the expert found the rationale provided either confusing, contradictory or inconsistent, in one instance a rationale was not provided for all decisions, and in one instance the reasoning for the choice of cues in successive steps was not clear to the expert.

Therapy Planning Forms recorded the original therapy set-up prior to the software being given to the participant, but also provided the opportunity to record subsequent adaptations as the PWA progressed through the therapy. Figure 4.7 shows the number of adaptations made after it was originally tailored by the SLT. 25% of participants had their therapy exercises adapted in some way following the original set up. In total 55 adaptations of the therapy were recorded. As adaptations could be made by the assistant/volunteer as well as the therapists it might be that more adaptations were made than were recorded, but the therapist was asked to record any changes including those made by assistants/volunteers. The therapy manual states that it is the responsibility of therapists to “monitor the appropriateness of the tailored exercises”, whilst not explicitly stated in the manual the reason for monitoring the appropriateness would be to make changes if necessary. The designers of the software particularly highlighted the importance of adapting the therapy in the interviews in chapter three (see page 87). As no explicit recommendation regarding adaptations was made in the protocol or therapy manual, this aspect of quality of delivery, highlighted to be important in the interviews in chapter three, has not been scored.

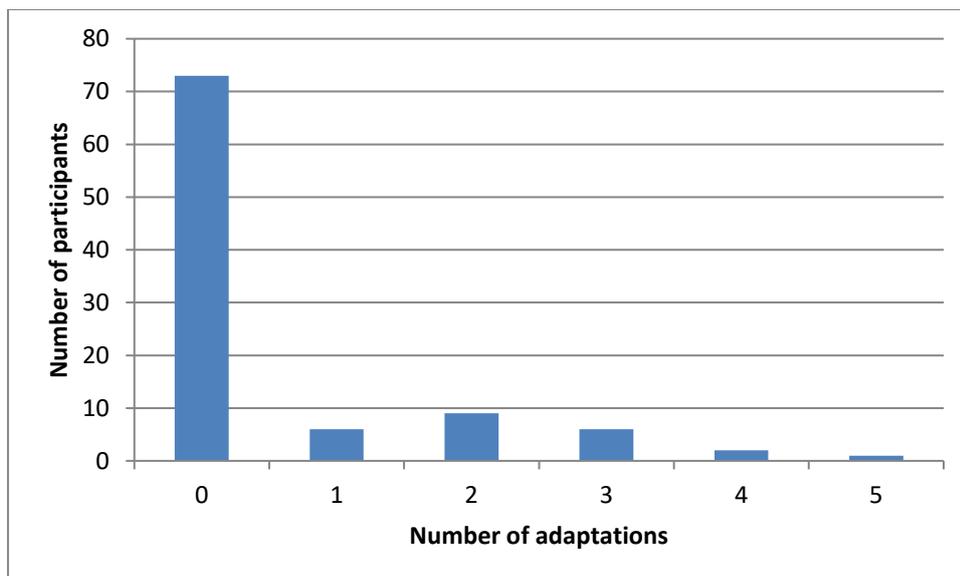


Figure 4.7. Bar chart showing the number of adaptations made to the therapy exercises following initial set-up (n=97)

As well as recording the number of adaptations made to the therapy after the original set up, details of the adaptations were also recorded on the Therapy Planning Form. A content analysis of the adaptations described identified eleven types of adaptations, which are

displayed in figure 4.8. The most common adaptation was the addition of new vocabulary. Therapists added new vocabulary when the participant was performing well with all existing vocabulary, the participant wanted a challenge or to motivate the participant to continue practising.

“Participant is achieving 90%+ scores on original 100 words so volunteer has added additional vocab topics.” R21/10

On seven occasions the voice recognition icon was hidden or the therapist advised the participant not to use the voice recognition icon due to incorrect feedback being provided to participants causing them frustration. In some of these instances therapists noted that they would add the record and playback feature instead or if already available encourage the participant to use this instead.

“Hid steps x2 because patient finding these too difficult due to frustrations with voice recognition.” R18/19

“All steps with voice recognition: Calibration/headset has not improved voice recognition so voice recognition option has been removed and replaced with audio record and playback where possible.” R21/10

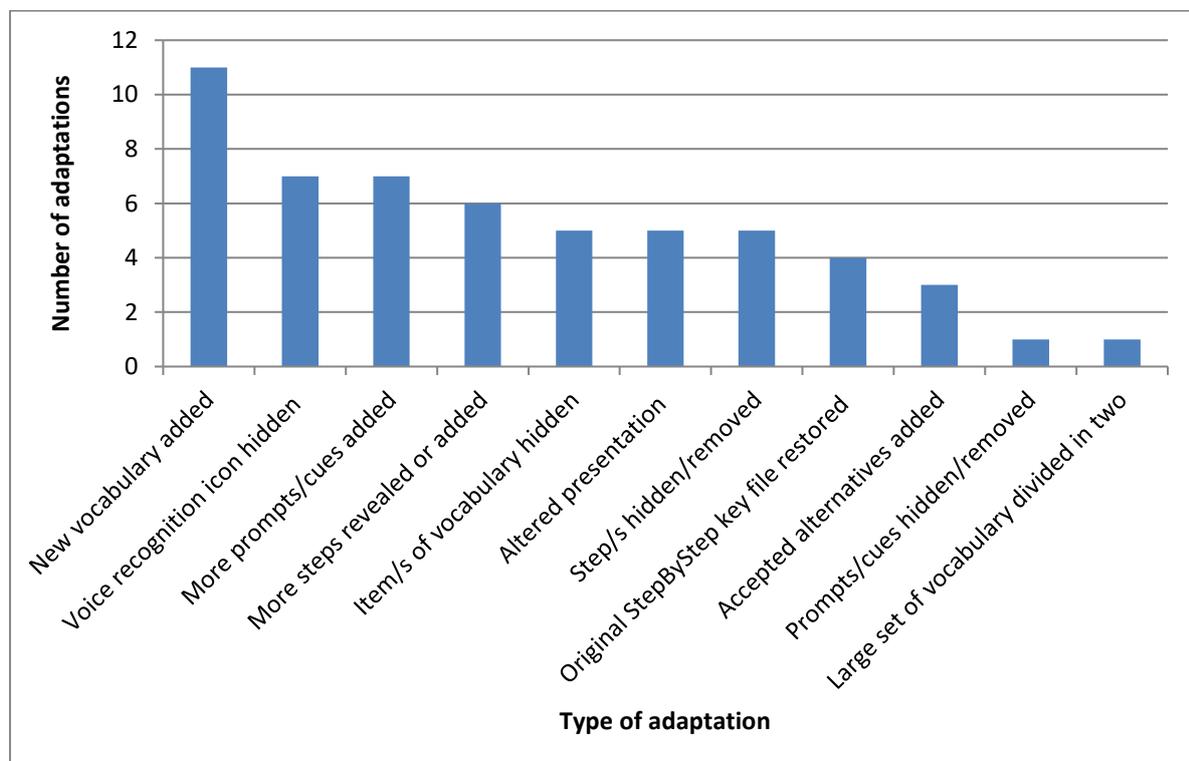


Figure 4.8. Bar chart type of adaptations made to the therapy following the initial set-up (n=55)

Another common adaptation (n=7) was adding prompts or cues to an existing step typically to provide more support.

"Step 2: Added written whole word cue as single spoken/written cue insufficient for recall, as became apparent during initial SLT/volunteer joint visit." R01/05

For other participants therapists described adaptations that involved revealing or adding steps to provide additional challenges and/or enjoyment for the participant.

"Feedback from assistant indicated participant working at sentence level. Created new exercises with sentence level steps for my places, music and numbers." R17/19

On five occasions items of vocabulary were hidden due to the subject being upsetting or frustrations with voice recognition relating to specific vocabulary items.

"Grid step: SLTA [Speech and Language Therapy Assistant] 'hid' some words (e.g. hippopotamus), which he was finding very frustrating. If he gets too frustrated he gives up and gets angry. Spelling step: 'orange' hidden as software not working properly for this item." R10/37

Other types of adaptation included: altering how the vocabulary items or exercises are presented by the software (n=5); hiding or removing steps due to participants finding them too difficult (n=5); restoring the original StepByStep key file due to software or hardware problems (n=4); accepted alternative of the word added due to local dialect or voice recognition problems (n=3); prompts or cues being removed due to not being helpful (n=1); and dividing a large set of vocabulary items because there were too many items in a single vocabulary topic (n=1).

To summarise, the purpose of the eleven types of adaptations made to the StepByStep software was to increase ease of use, either by removing impediments or providing more support, or to further challenge the participant.

Quality of delivery: Relationship between the PWA and the volunteer/assistant

The working alliance inventory (WAI-SRT; Hatcher & Gillaspay, 2006) was completed by the volunteer or assistant for 21% of participants in the intervention arm of the Big CACTUS study. The low response rate was due in part to ethics permission having been obtained after the window to collect the data had passed for approximately a third of the participants.

The mean alliance score on the WAI-SRT was 4 (maximum of 5; range 2.7-5) indicating the presence of a strong working alliance between the volunteer/assistant and the PWA. The sub-scale scores across the three dimensions of working alliance identified by Bordin (1979) were very similar: a) task: mean=4, range 2.7-5, b) bond: mean=4, range 2.8-5, and c) goal: mean=3.9, range 2.3-5. This suggests that the relationship between the PWA and the volunteer/assistant was a collaborative one based on agreed goals and the tasks needed to achieved these goals as well as a strong bond of mutual trust and personal liking.

The importance of the quality of the relationship between supporter and the PWA was not explicitly discussed in the protocol or therapy manual, however it was perceived to be an important component of the intervention to measure according to experts interviewed in study two (chapter three). The therapy manual implicitly makes reference to the importance of the relationship when it refers to the volunteer/assistant *supporting, encouraging, and working with* the PWA and helping them to *move onto harder tasks*. As such it has been assumed that a strong working alliance score between the volunteer/assistant and the PWA would be indicative of high quality of delivery for this intervention. Therefore the presence of a relatively high alliance score indicates that the quality of delivery was high.

Participant responsiveness: Motivation, ease of use and personalisation

Visual analogue scales were received for 36% (n=35) of participants randomised to the intervention arm (n=97). Delays in obtaining ethics permission for these questions to be sent out to participants resulted in the visual analogue scales only being sent to approximately two thirds of participants (n=56) resulting in a response rate of 63%. The questions relating to motivation and ease of use were not answered by 2 participants. The majority were completed by the participant (63%; n=22) rather than their carer.

The median level of motivation (1=very motivated) was 4/10 (range 1 to 9) indicating a moderate degree of motivation overall, but with a broad range of levels of motivation within the sample. Figure 4.9 demonstrates that there was a trend toward more participants being moderately to highly motivated.

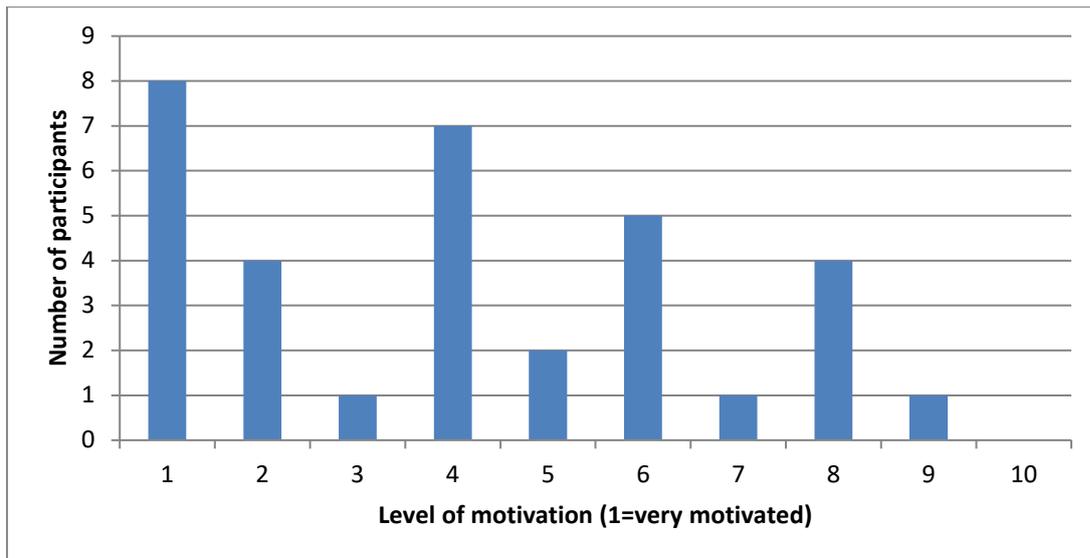


Figure 4.9. Bar graph showing perceived motivation to practice (n=33)

The perceived ease of use of the software (1=very easy) had a median score of 5 (range 1-8) suggesting that it was moderately easy to use. Figure 4.10 illustrates that perceived ease of use also had a varied response although it appears to show a bi-modal distribution with one group finding it very easy to use and another finding it moderately easy to use, however no participants felt it was 'not easy at all'.

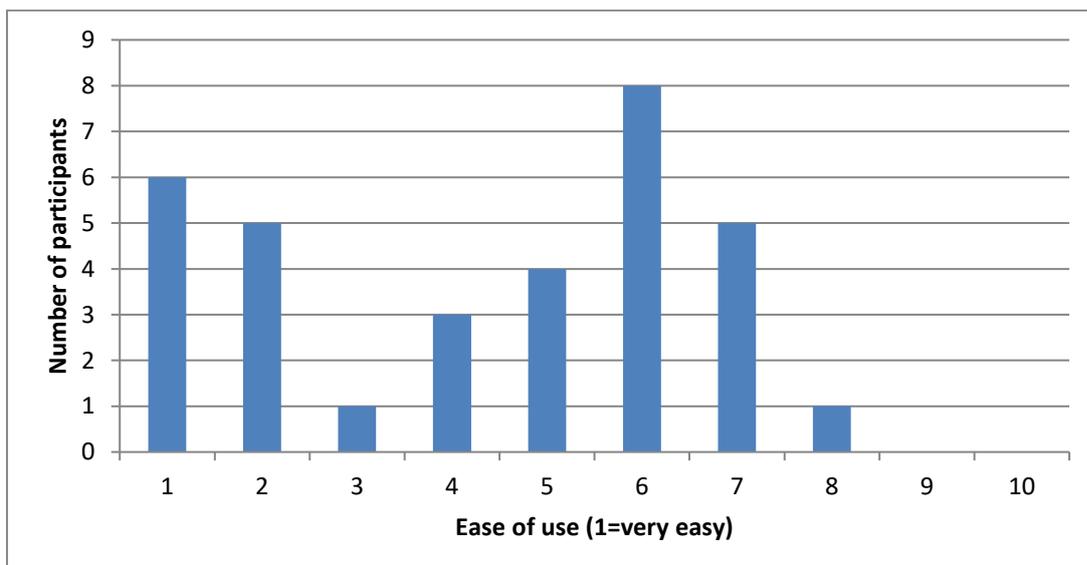


Figure 4.10. Bar graph showing how easy to use the software was perceived to be (n=33)

The question relating to personalised vocabulary was scored on a 5-point categorical scale. The median response was that it was perceived that participants were learning words they wanted to be able say 'most' of the time. The range of responses can be seen in figure 4.11.

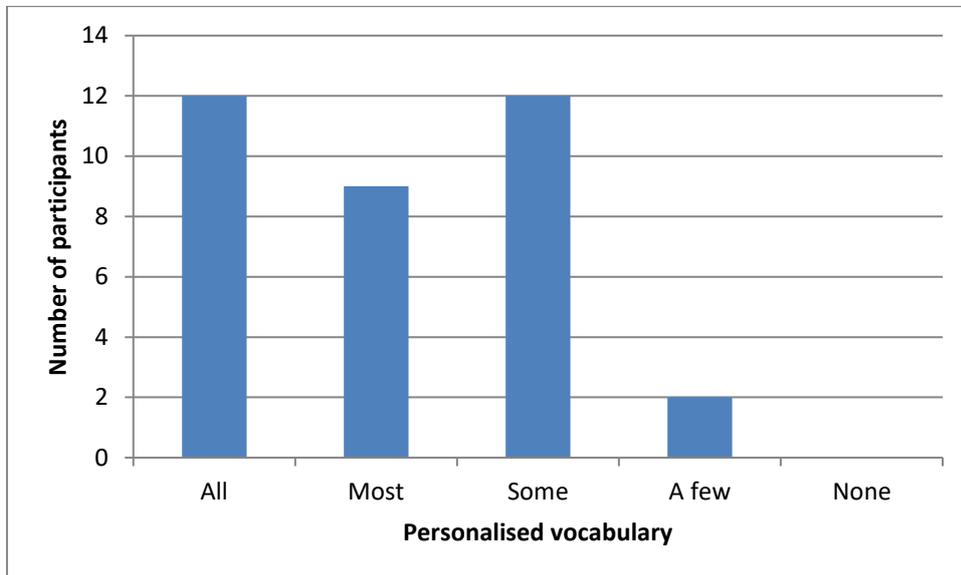


Figure 4.11. Bar graph showing that vocabulary was perceived to be personalised to some degree in all instances (n=35)

There was very little difference between the PWA and carer responses to each item. The score provided by carers was marginally less positive than that provided by PWA for all items.

Summary of moderators of adherence

Quality of delivery and participant responsiveness are two of the elements from the CFIF (Carroll et al, 2007) thought to moderate adherence. Results of the evaluation of quality of delivery and participant responsiveness are summarised in table 4.10. All measures of quality of delivery were scored as high or very high and measures of participant responsiveness as moderate or high.

Intervention component	What was measured	Actual delivery	Intended delivery based on therapy manual (TM) or protocol (P)	Degree of fidelity
Therapy set-up: personalising and tailoring	Therapist experience, training and learning effects	100% were qualified SLTs (AfC band 6-8) 100% of therapists delivering the intervention received training	“The SLT providing this intervention should hold a speech and language therapy qualification from an institution recognised by the Royal College of Speech and Language Therapists. The therapist should have experience of providing therapy to PWA as a consequence of stroke. They should have received training on how to use the software and provide the StepByStep intervention.” (TM)	Very high Very high
		Median score on lead therapist quiz of 10/15 (67%) at 5 month time point		High
	How therapy was tailored	Comprehensive understanding of the rationale how the therapy was tailored based on language profile for 66% of the sample of therapy planning forms	“Qualified SLT assessment of patient’s language profile to tailor computer exercises using the StepByStep© software so that they target the specific language deficit identified.” (TM)	High
		25% of participants had their therapy exercises adapted in some way. The purpose of the adaptations was to increase ease of use (either by removing impediments or providing more support) or to further challenge the participant	“Changes to the exercise set up and additional vocabulary can be made by the volunteer/assistant under the guidance of the therapist.” (TM)	N/A*
Personalisation	Median score of 4/5 = ‘most’ of the words were perceived to be of personal relevance (80%)	“Creation of exercises using target words of personal relevance to the patient.” (TM)	High	
Regular independent practice	Ease of use	Median ease of use score of 5/10 (1=very easy) (50%)	N/A	Moderate
	Motivation	Median motivation score of 4/10 (1=very motivated) (60%)	TM states that the software is designed and the volunteers/assistants are there to help “encourage motivation for self-managed practice”	Moderate

Supporting and monitoring use	Relationship between the PWA and the volunteer/assistant	Mean WAI-SRT score 4/5 (80%)	“The volunteer/assistant should [...] encourage use of computer exercises; check results and discuss difficulties; assist patient to move on to harder tasks [...]; encourage the use of new words in everyday situations through word games, conversation and discussions with family” (TM)	High
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Table 4.10. Summary of the findings of moderators of adherence (quality of delivery and participant responsiveness)

4.4 DISCUSSION

Synthesis of results

Throughout the findings sections the elements of fidelity (based on the CFIF; Carroll et al, 2007) of each component have been scored individually. Each component will be discussed in turn below to provide a comprehensive understanding of how the actual delivery of the intervention compared to the intended delivery specified in the therapy manual (Palmer, 2015) or Big CACTUS protocol (Palmer et al, 2017). Subsequent sections of the discussion will explore the findings of the process evaluation in relation to the Big CACTUS trial results and describe the strengths and limitations.

All participants randomised to the intervention arm of the Big CACTUS trial were granted access to the StepByStep software and the majority (82%) had access for the minimum recommended duration of four months within the six month intervention period. Both findings indicate very high fidelity using the five-point scoring system used throughout the findings section. Looking at the documentary evidence in more detail and comparing it to the optimal delivery duration (six months), however, demonstrates that there were issues with the fidelity with which this component was delivered. The median duration of access was 4.5 months and none of the participants had access for the optimal duration of six months. This was an artefact of the trial because the intervention period started at the point of randomisation despite it being understood that the therapist would need up to two weeks to set-up the therapy. Access delays greater than two weeks were experienced by 81% of participants. The reasons for delayed access included: the availability of the PWA and/or therapist, availability and issues with software and hardware and the length of time it took to set the therapy up.

The estimated duration of four hours therapy set-up time was delivered to 80% of participants, indicating high fidelity. The median amount of SLT time documented was 7.6 hours, this was almost double the estimated time, and significantly longer than the average amount of time SLTs spent setting up therapy in the pilot study (4 hours 43 minutes; Palmer et al, 2012). A breakdown of SLT activities was not collected in the pilot study, but data presented in this chapter shows that more than half of the SLT time (4 hours) was spent tailoring the therapy. Contextual factors, such as using StepByStep v5 before it was commercially available and trial procedure, might have increased therapy set-up time. Trial procedure dictated that personal vocabulary items had to be selected before the exercises were tailored, because personal vocabulary was needed for the naming assessment conducted prior to randomisation, but tailoring was only carried out following randomisation to the intervention group. Had tailoring happened first the software would have automatically

applied the same exercises to all vocabulary topics, but because the vocabulary was added first, the exercises had to be manually applied to each vocabulary topic. This may have contributed to the lengthy therapy set-up time, but would not necessarily apply to implementation outside of the trial.

The reporting of other aspects of adherence of the therapy set-up component were divided according to whether the SLT was supporting the PWA or the volunteer/assistant. All participants had input from the SLT in terms of setting up the therapy. Furthermore, SLTs carried out some training, support or monitoring of the volunteer/assistant supporting the majority of participants (93%). Thus, the coverage of the therapy set-up component was delivered with very high fidelity. The activities (i.e. content) documented for this component demonstrated that SLTs: delivered training to 92% of participants' volunteers/assistants (indicating very high fidelity); provided complete documentation regarding the tailoring of exercises for 65% of participants (indicating high fidelity); monitored the progress of approximately 50% of participants either directly or indirectly via volunteers/assistants (indicating moderate fidelity). The importance of monitoring how the PWA is engaging with the exercises, primarily achieved through two-way communication between the therapist and the volunteer/assistant, was highlighted by key informants in study two (chapter three). The StepByStep approach is designed to be tailored to the individual's abilities, but abilities are expected to change over time. Consequently, the absence of monitoring for approximately half of participants means that adaptations to ensure the exercises continued to be tailored to the individual's needs would not have been carried out.

Many of the measures of quality of delivery pertained to the therapy set-up component. All therapists delivering the intervention had received training and were appropriately qualified, indicating very high fidelity. The median score on the initial lead therapist quiz was 10/15 (67%), indicating high fidelity. The median score continued to increase at subsequent time points suggesting that the learning process continued whilst they were delivering the therapy. The therapy was tailored to the needs of the individual in a way that could be comprehensively understood by a StepByStep approach expert for 66% of participants, indicating high fidelity. Adaptations to the therapy exercises were made for a quarter of participants in order to increase the ease of use or further challenge the PWA. The measure of participant responsiveness indicated that participants perceived that most of the words they were practising were of personal relevance, indicating high fidelity.

Overall the 'therapy set-up: tailoring and personalisation' component was delivered with high fidelity, with most elements having been delivered with high to very high fidelity, but one aspect, monitoring of progress, having been delivered with moderate fidelity.

Regular independent practice of the word-finding exercises on the StepByStep software was self-managed by the PWA. Therefore, this component of the intervention was not 'delivered', as is usually described in fidelity evaluations, but it was 'received'. The frequency and duration of independent practice have been reported in the adherence section of this chapter, but they could also have been reported in the participant responsiveness section as they are also a measure of how well participants have engaged with the intervention. Half of participants practised for the minimum recommended duration of 26 hours and the minimum recommended frequency of three times per week, indicating moderate fidelity. It is possible that the reduced availability of the StepByStep software reduced the total amount of practice carried out by participants within the six month supported intervention period. The fact that the median practice duration and frequency are the same as the suggested time specified in the protocol is not surprising as the protocol was based on what was deemed to be achievable in the CACTUS pilot study, which found that participants practised for 25 hours over a five month intervention period (Palmer et al, 2012). On average the software was perceived to be moderately easy to use, but the bimodal distribution demonstrated there were a group of participants that found it very easy to use and a group of participants who found it moderately easy to use. On average participants felt that they were moderately motivated to engage in practice of aphasia computer therapy exercises. Overall, the regular independent practice component was 'received' with moderate fidelity, making it the lowest scoring component of the intervention, compared to others that were 'delivered' in a more traditional sense.

Supporting and monitoring use by a volunteer/assistant was the component with the lowest coverage, but it was still delivered to 89% of participants, indicating very high fidelity. The minimum recommended duration of support and monitoring of 4 hours was delivered to 55% of participants, indicating moderate fidelity. Whereas the minimum recommended frequency of 4 sessions was delivered to 77% of participants, indicating high fidelity. The median duration of volunteer/assistant support was 4.25 hours meaning that they spent, on average, less time than the therapist delivering the intervention, which is contrary to the recommendations from the therapy manual (Palmer, 2015). In terms of the content of support provided by the volunteers/assistants, 99% received encouragement and motivation to use the computer and 85% engaged in conversations, word games and/or discussions with family about how to encourage use of their words in context, indicating very high fidelity. Encouraging and motivating use was an important aspect of their role and had it not have been delivered the amount of independent practice might have been even lower. The median time spent engaged in activities to practise using their words in context was only 45 minutes (range 5 minutes – 2 hours 35 minutes). This was a very small proportion of the

total therapy time considering it was a feature perceived by key informants in chapter three, to be essential to generalise word-finding improvements to everyday activities. Interestingly, the word games referenced in the therapy manual were not described in the volunteer/assistant handbook (see appendix A of the therapy manual; Palmer, 2015). The findings from the working alliance inventory suggested that there was, on average, a strong relationship between the volunteers/assistants and the PWA they were supporting, indicating high fidelity. Fidelity across the supporting and monitoring use component has been classed as high, with individual elements ranging from moderate (duration) to very high (coverage and content).

Overall, the StepByStep approach to aphasia computer therapy was delivered with a moderate to high degree of fidelity. According to the scoring system the StepByStep software component was delivered with a very high degree of fidelity, however the narrative synthesis demonstrated some significant issues around access delays. The ‘therapy set-up: personalising and tailoring’ component and the ‘supporting and monitoring use’ component were both judged to have been delivered with a high degree of fidelity overall. SLTs provided more input than expected and volunteers/assistants less. However, the most notable findings were the lack of monitoring of participant progress (expected to occur through two-way communication between the SLT and the volunteer/assistant), which may have prevented adaptations to a therapy designed to be tailored to the individual’s abilities; and the limited time spent by volunteers/assistants encouraging the use of new words in context. The component with the lowest degree of fidelity was regular independent practice, which was received with moderate fidelity. It is possible that delays in accessing the StepByStep software (which reduced the duration of access) and the limited amount of volunteer/therapist support (one of their roles was to encourage and motivate practice), could have reduced the amount of practice carried out by PWA.

Synthesis of process and outcome data from the Big CACTUS trial

One of the purposes of evaluating fidelity to the StepByStep approach within the Big CACTUS trial was to improve our understanding of the outcomes of the trial through better understanding of the cause of the outcomes. The Big CACTUS trial found that aphasia computer therapy contributed to a significant improvement in word-finding of personally relevant words (compared to usual care or attention control), but these gains did not lead to improvement in conversation or quality of life. The cost-effectiveness of the trial was uncertain, but the intervention was more likely to be cost-effective for those with mild/moderate word-finding difficulties (Palmer et al, 2019; for more details about the trial see chapter one, page 37). Since the intervention as a whole was delivered with moderate to

high fidelity, the positive word-finding outcomes indicate that this level of fidelity was sufficient to cause improved word-finding ability. This suggests that delivery of the intervention at this degree of fidelity was sufficient to result in clinical gains. As described in chapter three, the intervention is complex and it is the complex interplay of the four components that is expected to achieve the desired outcomes. However, it is possible to consider the potential impact delivery of individual components might have had on the outcomes of the trial.

Only ten participants randomised to the computer therapy group did not improve their word-finding ability, of whom seven had carried out less than five hours computer practice (Palmer et al, in press). Regular independent practice was judged against a minimum criteria of 26 hours, with an implicit assumption that more practice would lead to more clinical gains. The relationship between the amount of independent practice and word-finding ability was reported stratified by severity. The findings demonstrated that those with severe word-finding difficulties seemed to benefit more from greater amounts of practice, whereas benefits for those with mild/moderate word-finding difficulties diminished beyond 26 hours of practice (Palmer et al, 2019; supplementary material, page 59). As described above, the median time spent practising the three confrontation naming exercises was comparable to the median time spent on the 'using writing to cue naming' exercise, which was potentially being used as a spelling task. It is possible that participants with mild/moderate word-finding impairments who practised for long durations were working on this therapy exercise, in order to improve their spelling, which would not convey clinical gains on a measure of word-finding. This will be explored further in the component analysis in chapter six.

The finding that improved word-finding ability (i.e. impairment) did not translate to improved conversational ability (i.e. activity) or quality of life (i.e. participation) warrants further exploration from a fidelity perspective. The intervention components potentially associated with translating word-finding gains into improved conversation include: 1) salience of target words achieved through personalisation of vocabulary so participants were learning words they wanted to say in their day-to-day lives; and 2) it was intended that volunteers/assistants would "encourage the use of new words in everyday situations through word games, conversation and discussions with family about how to encourage use" (Palmer, 2015). The only data collected about personalisation was the self-reported participant responsiveness question. The median response was 'most' of the words were personally relevant and no participants perceived the words not to be personally relevant. In addition, all participants had a naming assessment carried out, which had to be populated in the StepByStep software separately for each individual, thus indicating words had been selected for each participant. The limited data collected suggests fidelity to personalisation was high, therefore

this does not provide a potential explanation for the Big CACTUS trial finding that improvement did not generalise to functional communication. Future fidelity evaluation of this intervention would benefit from further exploration of this component. Activity logs recorded volunteer/assistant time spent encouraging the use of new words in everyday situations. Whilst 85% of participants received some degree of encouragement to use their words, the median amount of time spent delivering this component was only 45 minutes. Considering the computer therapy exercises to improve word-finding (which was successful) were carried out for a median of 26 hours this makes the time spent on practicing in conversation, a potentially important component for generalisation to conversation, appear negligible. Further intervention refinement around this component could include greater emphasis on this component in the training (as only one therapist recognised it as a key component on the lead therapist quiz), additional guidance within the volunteer/assistant handbook on how to practise using words in conversation with the PWA, and recommendations about the amount of time volunteers/assistants are expected to spend on this component. However, it is worth noting that these recommendations rely on the assumption that practising words in context helps with generalisation, which has not yet been clearly established in the aphasia literature and would therefore also benefit from further research.

The health economic evaluation found uncertainty around whether the intervention was cost-effective (Palmer et al, 2019). This is contrary to the findings from the pilot CACTUS trial, which indicated that the intervention was very likely to be cost-effective (Palmer et al, 2012). One of the primary differences between the two studies was the cost of SLT time due to the increased amount of time SLTs spent setting up the software in the Big CACTUS trial compared to the pilot, which might partially explain the differences. As described above, artefacts of the trial, such as the order in which personalisation was carried out, might have resulted in additional time having been spent by SLTs that would not be applicable when the intervention is implemented in clinical practice. However, intervention designers might also want to consider providing more detailed advice around the most time efficient ways of tailoring and personalising the software.

Strengths and limitations

Fidelity evaluation typically involves observational methods, but they were impractical for this geographically diverse study population where much of the therapy was delivered through self-managed practice. Whilst not having observational data could be viewed as a limitation, the advantage is that the majority of data sources for this fidelity evaluation were collected across the total population receiving the intervention, which is thought to increase the validity of the findings (Moore et al, 2015) and contrary to the common practice of evaluating the

fidelity of a small sample of participants for the sake of efficiency (Schoenwald et al, 2011). Unlike many self-managed interventions this computer-based therapy was able to reliably record the amount of time spent carrying out independent practice and the different therapy exercises participants had completed.

A further strength is the wide breadth of the fidelity assessment evaluating delivery of all of the key components of the intervention as identified by key informants, and multiple aspects of fidelity as defined by the CFIF (Carroll et al, 2007). Furthermore, the fidelity evaluation not only measured things that had a direct standard for comparison, but also explored contextual factors of fidelity, such as reasons for delayed access, in order to provide context in which to situate the more objectively measured aspects, such as frequency and duration of practice. However, focusing solely on aspects of fidelity meant that wider information about the context within which the intervention was delivered, typically collected by a process evaluation, was not considered, thus excluding important contextual factors, such as the economic, political and organisational context in which the intervention was embedded (Masterson-Algar et al, 2016).

It is possible that the relationship between the author and the study staff implementing the intervention was too close. The author had a second role within the trial that involved delivering some of the training to study staff, visiting them at site to monitor progress and regular contact with therapists delivering the intervention regarding data collection queries. The MRC process evaluation guidance refers to the challenge of maintaining good working relationships whilst also remaining independent to ensure the evaluation is not unduly positive or critical (Moore et al, 2015). Whilst frustrations with individuals and sites were experienced by the author, they were short lived and the physical distance between all except two of the study site staff and the author ensured that most communication was by the more formal modes of email, phone call or teleconference, which afforded a degree of independence. In addition, where possible, quantitative data was rated or analysed blind to site to reduce the influence of personal opinions.

The process of scoring and averaging scores in order to compare fidelity across components and elements of the fidelity framework was problematic as it did not take into account the relative importance of the different components of the intervention or aspects of fidelity (for example is coverage more important than frequency or regular independent practice more important than support and monitoring?). Several of the measures were proxy measures (e.g. Therapy Planning Form was a proxy for quality of delivery) with the potential for different outcomes had a different proxy or direct measure have been available. Furthermore, the validity and reliability of the different data sources was variable, including usage data

captured electronically, self-report measures recording direct and indirect time with participants and other validated scales, such as the working alliance inventory (Hatcher & Gillaspay, 2006). Components of the intervention were not evaluated to the same extent, for example tailoring of the intervention was assessed through three different means, but adherence to SLTs personalisation of therapy set-up was not recorded. This was an artefact of the trial because selection of personally relevant vocabulary was required to create the naming assessment for all trial participants prior to randomisation so it was not recorded on the activity logs, which only collected information specific to the intervention arm group.

Conclusion

Overall, the StepByStep approach intervention was delivered with moderate to high fidelity in the Big CACTUS trial. The 'StepByStep software' component was delivered with very high fidelity, having been provided to all participants and the majority having had access for the minimum recommended duration. The 'therapy set-up: personalising and tailoring component' was delivered with high fidelity. All participants received input from an SLT with the majority receiving more input from the SLT than expected. As well as tailoring of the intervention, which was delivered with high fidelity, SLTs were expected to monitor the support provided by the volunteer/assistant, but this was carried out for less than half of participants. 'Regular independent practice' was received with moderate fidelity. This component was self-managed by the PWA and half of participants carried out the recommended minimum frequency and duration of practice. The 'supporting and monitoring' component was delivered with high fidelity with the majority of participants receiving input from a volunteer/assistant. Approximately half of participants received the recommended minimum duration of input, but most received the minimum recommended frequency of sessions. Whilst the majority received encouragement to use new words in everyday conversation, the average duration of this component was 45 minutes per participant. This was one of the aspects of the intervention that was anticipated to result in improved conversational ability, an outcome in the Big CACTUS trial that was not found to have improved for the intervention group. It is therefore recommended that this component of the intervention (encouragement to use new words in everyday conversation) requires further refinement in future studies. The next chapter will explore adherence to the intervention in more detail by exploring the factors associated with adherence to independent practice of the StepByStep approach to aphasia computer therapy.

Chapter Five: Exploring the Factors Associated with Adherence to Aphasia Computer Therapy Practice: A Mixed Methods Investigation

This chapter will focus on one specific aspect of fidelity, adherence, particularly to the dose of therapy. A mixed methods approach was adopted to explore the factors associated with adherence to aphasia computer therapy practice, including qualitative exploration of the views of people with aphasia (PWA) and their carers and quantitative analysis of the demographic, clinical or intervention variables associated with adherence.

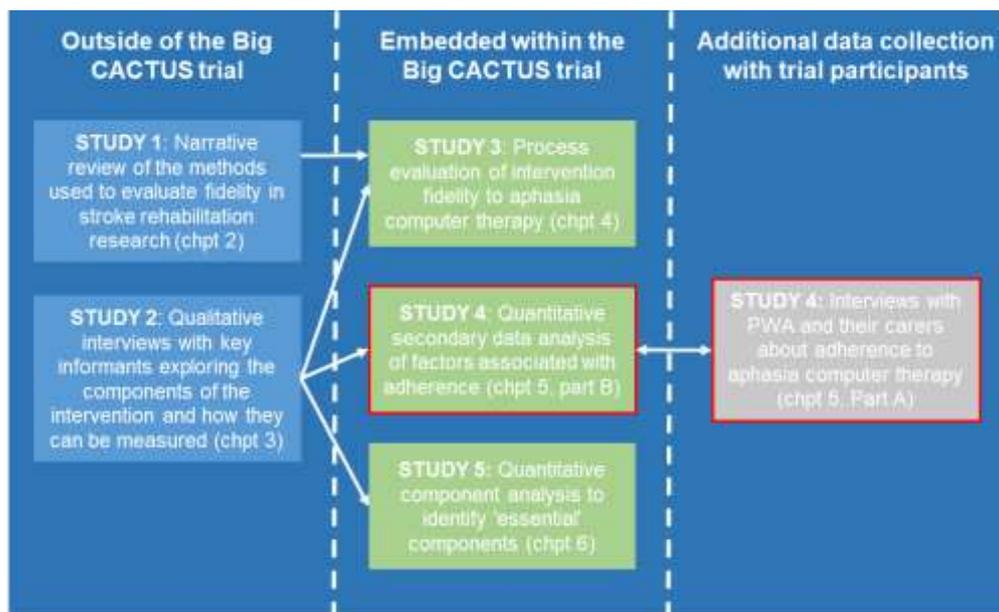


Figure 5.1. PhD structure: red border indicates current chapter

5.1 INTRODUCTION

Adherence is a fundamental element of fidelity. According to the Conceptual Framework for Implementation Fidelity adherence encompasses coverage (whether those who should receive the treatment actually do), content (substance of the intervention), frequency (treatment intervals) and duration (length of time) (Carroll et al, 2007). The elements of adherence focused on in this chapter are frequency and duration, which are more commonly referred to together as dose. Dose can therefore be achieved through high intensity (i.e. massed) practice over a short period of time, or lower intensity (i.e. distributed) practice over a longer period of time (Doogan et al, 2018). A Cochrane Review demonstrated aphasia therapy was more effective when delivered at a high intensity, high dose or over a longer duration (Brady et al, 2016). However, the clinical benefits of high dose and high intensity therapies were confounded by higher dropout rates indicating that these interventions might not be acceptable to all (Brady et al, 2016). There is ongoing debate about whether it is the total dose or intensity of therapy that enables therapy to be most effective, however irrespective of favouring massed or distributed practice there is agreement that more is better (Doogan et al, 2018).

Computerised speech and language therapy is thought to be a cost-effective solution to provide more therapy in the longer term, as it provides maximum opportunity for practice with less SLT input (Zheng et al, 2016). However, providing the opportunity for more therapy and the PWA actually carrying out more therapy do not necessarily equate. When delivered as a self-managed intervention, participants can decide to carry out as much or as little practice as they want. Understanding reasons for variation in adherence to aphasia computer therapy might help speech and language therapists to target computer therapy at those who are most suited to this approach. As such, this chapter will focus on understanding the factors associated with participant's adherence to aphasia computer therapy.

The primary measure of adherence for the purpose of this study was total practice time over the six month intervention period (i.e. dose) with more practice indicating greater adherence. The 'StepByStep approach for the NHS' therapy manual and 'StepByStep v5 user guide' given to all participants prior to commencing computer therapy practice recommend the computer therapy should be used for 20-30 minutes per day for six months (i.e. 61 hours to 91 hours; Palmer, 2015). However, taking into consideration periods of holiday, illness and weekends the minimum amount of practice time considered to be 'per protocol' for the purpose of statistical analysis in the Big CACTUS trial was 20 minutes three times per week for six months (i.e. 26 hours). No maximum amount of aphasia computer therapy practice

was recommended in the Big CACTUS trial due to the lack of a known optimal dose of aphasia therapy (Palmer et al, 2017; Palmer, 2015).

Behaviour change theory

Asking someone to engage in regular practice of aphasia computer therapy exercises requires them to change their behaviour. The COM-B system states that it is a combination of capability, opportunity and motivation that determines whether or not a behaviour will be enacted (see figure 5.2; Michie et al, 2011). The authors have theorised the direction of the relationships between the four interrelated factors, such that opportunity and capability can influence the degree of motivation, whereas capability, opportunity and motivation all have a bidirectional relationship with behaviour. The four elements of the COM-B framework can be further sub-divided. Capability is divided into physical and psychological capability, with physical capability referring to elements such as physical strength and skills, and psychological capability referring to having the psychological resources and skills to comprehend and perform the behaviour (Michie & West, 2013). Opportunity is divided into the opportunity provided by the physical and social environment. The physical environment relates to aspects such as resources or location and social environment relates to aspects such as culture and language. Motivation is divided into reflective and automatic processes. Reflective processes require planning and evaluation, whereas automatic processes are based in basic drives, emotional responses, learnt associations and habit (Michie et al, 2011).

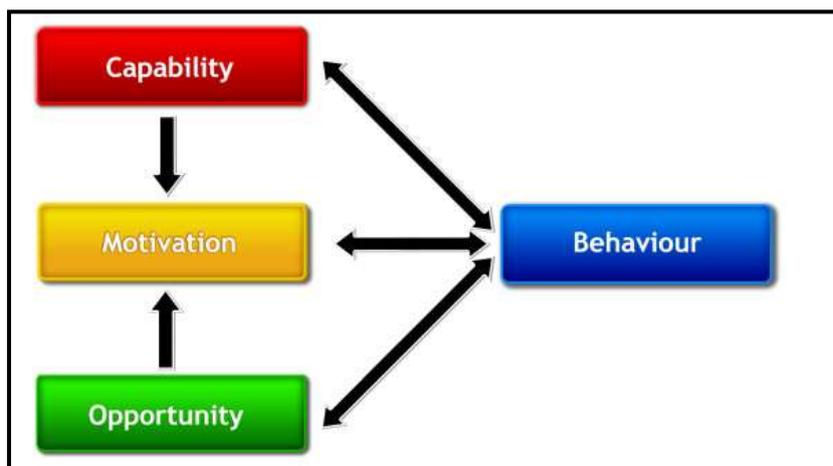


Figure 5.2. The COM-B system (Michie et al, 2011 ; licenced under CC BY 4.0; reproduced with no changes)

An additional framework, has been mapped onto the COM-B system, by Cane and colleagues (2012), to provide further detail of the theoretical domains relevant to behaviour change encompassed within each aspect of the system (see table 5.1). The authors of the Theoretical Domains Framework (TDF) have combined different theories of behaviour change in order to integrate and simplify the large number of behaviour change models available in the literature (Cane et al, 2012). A theoretical domain was defined as “a group of related theoretical constructs” relevant to behaviour change (Cane et al, 2012). All TDF domains are mapped onto the COM-B system, although three domains (skills, social/professional role & identity and optimism) are included in two sub-elements. As a result of the comprehensive nature of the COM-B system of behaviour change and TDF domains, the author decided that these should serve as the sensitising framework for the exploration of the factors associated with adherence to aphasia computer therapy practice.

COM-B elements		TDF Domain
Capability	Psychological	Knowledge
		Skills
		Memory, Attention and Decision Processes
		Behavioural Regulation
	Physical	Skills
Opportunity	Social	Social Influences
	Physical	Environmental Context and Resources
Motivation	Reflective	Social/Professional Role & Identity
		Beliefs about Capabilities
		Optimism
		Beliefs about Consequences
		Intentions
		Goals
	Automatic	Social/Professional Role & Identity
		Optimism
		Reinforcement
		Emotion

Table 5.1. Mapping of the COM-B system to the TDF Domains (Cane et al, 2012; licenced under CC BY 4.0; reproduced with no changes)

Rationale and aim

As described above the optimal dose of aphasia therapy is not known, however evidence suggests that aphasia therapy delivered at a higher dose is more beneficial (Brady et al, 2016). As such, for the purpose of this study, more practice equals greater adherence. The self-managed computer aphasia therapy trialled in the Big CACTUS study provided the opportunity for participants to engage in as much or as little therapy as they chose over a six month period with SLT and volunteer/assistant support. It is not known why some participants carry out more practice than others. Consequently the overarching aim of this study was to explore the factors associated with adherence to aphasia computer therapy practice. A mixed methods approach was adopted with the following objectives:

1. factors perceived to influence the amount of aphasia computer therapy practice carried out were identified from the perspective of both low and high adhering PWA and their carers;
2. patient, clinical and intervention related characteristics associated with adherence to aphasia computer therapy practice were identified through secondary analysis of data collected in the Big CACTUS trial; and
3. the two data sources were synthesised to cross-validate the findings.

5.2 MIXED METHODS APPROACH

A concurrent triangulation mixed methods approach was adopted to explore the factors associated with adherence to aphasia computer therapy (Creswell, 2003). The qualitative exploration of adherence was able to explore a wide range of factors associated with adherence, whereas the quantitative exploration was only able to include factors for which data had been collected within the Big CACTUS trial. Employing a concurrent triangulation approach ensured a greater breadth of possible factors were explored in the qualitative interviews, which would not have been possible using quantitative data from the Big CACTUS trial alone. Furthermore, where the same factors were explored in both datasets it allowed us to seek convergence in order to cross-validate the findings (Morgan, 1998). Using mixed methods in this context therefore enabled greater understanding than if either of the parts were conducted in isolation (Barbour, 1999).

As described in the first chapter (page 42), the author approached the thesis from a subtle realist stance meaning that we only know reality from our own perspective of it. Consequently, the author placed equal value on the qualitative and quantitative aspects, whilst acknowledging the key limitations of both approaches for exploring the question in hand. These limitations included: the difficulty of obtaining high quality qualitative data from a population with significant communication impairment (Bronken & Kirkevold, 2013), and the inherent weakness of secondary data analysis being that the data was not collected with the current research question in mind and therefore may not include all of the data required to answer this research question.

The chapter is divided into three sections: a) qualitative interviews, b) secondary data analysis, and c) integration of qualitative and quantitative findings. The method, results and summary discussion of each of the three sections are described in turn followed by a combined discussion including strengths and limitations, clinical implications and considerations for future research.

5.3 PART A: QUALITATIVE METHOD

Design

Qualitative interviews were employed to enable an in-depth exploration of the factors perceived to influence the amount of aphasia computer therapy practice carried out from the perspective of PWA, and their carers, who have experience of using the StepByStep intervention in the Big CACTUS study. Typically qualitative researchers seek out informants who can provide high-quality data through articulate and reflective description of their experiences (Paterson & Scott-Findlay, 2002). Communication impairments, such as aphasia, make this more challenging (Bronken & Kirkevold, 2013). Since this is an intervention for PWA it was essential that they participate in the interviews, where possible. Strategies to facilitate involvement of PWA and ensure the production of the best possible quality of data included working collaboratively with the Big CACTUS Patient and Carer Advisory Group to develop the interview schedule and picture cards of key concepts to help participants to respond when they can't express themselves, and employing a 'total communication approach' during the interviews (using facial expressions, gesture, writing key words and drawing) (Johansson et al, 2012).

Eligibility criteria

Participants with the most severe aphasia, who were unable to comprehend two key words in a sentence according to the Consent Support Tool (Jayes & Palmer, 2014), were excluded from this research as it was unlikely they could be supported sufficiently to understand the questions asked. However, in order to ensure that the data collected was representative of the diversity within the whole Big CACTUS sample, carers of people who were unable to comprehend two key words in a sentence were included in a carer-only interview.

Patient participant interview eligibility. Participants were eligible to be contacted if they had: 1) completed the intervention phase in the Big CACTUS trial (i.e. six months post randomisation), 2) previously agreed to be contacted about future research, and 3) were based at one of the ten Big CACTUS study sites closest to the author's location (Sheffield), see figure 5.3. Patient participant interviews were conducted in-person to enable the author to use supportive communication strategies and by selecting the closest ten sites the time and expense associated with travel were reduced whilst still allowing a diverse range of experiences to be explored including a variety of different therapists and a mixture of rural and urban settings. If a patient participant had a relative or carer who supported them to use the computer therapy then the relative or carer was automatically eligible for participation.



Figure 5.3. Map showing Big CACTUS site locations; PWA participants recruited from sites inside the dashed rectangle

Carer-only interview eligibility. Carers from all sites were eligible for inclusion in a telephone interview if they met the following criteria: 1) the patient participant they care for was randomised to the intervention arm of the Big CACTUS trial more than 6 months ago, 2) the carer previously agreed to be contacted about future research. At the time of recruitment to this study approximately one quarter of participants recruited to the Big CACTUS study were unable to understand two key words in a sentence, thus to ensure the representativeness of this sample approximately one quarter of invitations were sent to carer-only participants.

Sampling strategy

Maximum variation sampling was used to identify a heterogeneous sample comprising participants who had carried out the highest and lowest amounts of total practice in order to maximise the diversity of experience within the sample, as well as enabling the identification of important shared themes that cut across cases (Patton, 1990). Total practice time was automatically recorded by the StepByStep software key file.

Big CACTUS trial participants who met the eligibility criteria were listed according to the total amount of practice time they had carried out in the six-month intervention period. Working inwards, those at the top and bottom of the list were invited to participate first to increase the heterogeneity of the sample. As the trial was on-going, the number of participants completing the six-month intervention period continued to increase and the list was therefore updated during the process of data collection for this study.

Sample size

Sample size was determined by the concept of data saturation, which states that data collection stops when no new themes emerge from the data (Glaser & Strauss, 1965). See data analysis section for more detail.

Recruitment and consent

Participants were approached via an invitation letter and information sheet, in an accessible format for patient participants, followed by a telephone call from the author. If the participant was interested in taking part the date, time and location for the interview was arranged. Recruiting participants with aphasia, a condition that can prevent people from talking and writing as well as understanding spoken and written communication, required a tailored approach to recruitment and consent (Jayes & Palmer, 2014). The Big CACTUS trial's Patient and Carer Advisory Group's opinions were sought in the development of all accessible materials. As well as determining which participants were eligible to take part in the study, the results of the Consent Support Tool (CST; Jayes & Palmer, 2014) conducted during the recruitment of participants to the Big CACTUS trial, were used to decide which participant information sheet was provided. If the CST determined that the participant understands written paragraphs they were provided with the standard participant information sheet. If the participant was found to understand between two and four key written and spoken words in a sentence the accessible information sheet (large font, key words emboldened and pictures to represent concepts) was provided in advance of the interview and on arrival the author went through a power point slideshow containing the same information. The author asked the participant questions to ensure they understood the content of the information sheet before they were asked to sign the consent form.

Carer-only interview participants were sent a carer-only information sheet and carer consent form. The author spoke to the carer on the telephone to establish their interest, provide an opportunity to ask questions and arrange a time and date for the telephone interview. The carer participant was asked to return the signed consent form by post prior to the date of the telephone interview.

Procedure

The interviews were conducted whilst data collection was on-going for the Big CACTUS trial. The interviews took place face-to-face or over the phone depending on whether a PWA was taking part. The author sought to interview the patient and the carer separately, where possible, to allow the PWA to share their views without interruption. Informal carers who did not participate in the Big CACTUS study were asked to complete a short form collecting

basic demographic information already collected about the informal carers participating in the Big CACTUS study (e.g. sex, date of birth and relationship to PWA; see appendix S). The interviews were recorded using a digital recorder and transcribed verbatim. All transcriptions were checked for accuracy.

Data collection

Three approaches to data collection were combined in the semi-structured interviews to enable participants with aphasia to generate their own responses to express their views where possible, but also to facilitate their contribution through confirming or refuting the perceptions of the Big CACTUS trial Patient and Carer Advisory Group. The interview schedule comprised 1) open-ended questions requiring a spontaneously generated response, 2) questions with visual analogue scales to support the participant to respond, and 3) questions that could be answered using a picture selection task. This method has been used previously when interviewing PWA about the acceptability of computer therapy in a pilot trial of the same intervention (Palmer et al, 2013).

Interview schedule. The development of the interview schedule (see table 5.2) was influenced by the COM-B system of behaviour change described on page 155 (Michie et al; 2011) and Meichenbaum and Turk's (1987) seminal work on adherence that described a typology of the determinants of adherence falling into 5 broad categories: patient, disease, treatment, healthcare professional and organisation. Once drafted, the interview schedule was shown to the Big CACTUS trial Patient and Carer Advisory Group who suggested changes to the wording to increase the accessibility of the language used. The interview schedule for patient participants was colour coded (see figure 5.4; appendix T). The questions shown in green were grammatically and conceptually simple and were supported by a visual analogue scale, visual prompts or cues (i.e. calendar) or a picture selection task to support the participants to respond (see appendix U for materials to support the interview schedule). Questions shown in orange (more grammatically and conceptually complex) were asked only of those participants who were able to answer the green questions with ease. Red questions (the most conceptually challenging) were only asked of those participants who were able to answer the orange questions with ease. The first interview served as an internal pilot after which the author reflected on how the questions were asked and the answers that were forthcoming and made small changes in the wording of the questions as necessary.

How often did you see [therapist name] and how long for? *[Show picture of therapist and calendar and clock]*

- Can you tell me about your relationship with [therapist name]?
- How did [therapist name and volunteer name] feel about the computer therapy?

Figure 5.4. Example of colour coding from interview schedule

The carer interview schedule asked similar questions re-worded to ensure the questions were appropriate for the PWA’s informal carer (see appendix V). One additional question was added to explore the impact of the patient using the computer therapy on the informal carer. In instances where the carer participants agreed to be interviewed separately and the PWA was able to answer most questions with ease, the carer was only asked to fill in any gaps noted by the author during the interview and to answer the final question about how the PWA’s use of the aphasia computer therapy impacted upon them.

Interview schedule
How much does your communication problem affect your life? Can you tell me about how your communication problem affects your life?
How important is it to you that your communication problem improves?
How much speech therapy have you had before? Can you tell me about the speech therapy you have had before?
When [therapist name] told you about the computer therapy, what were your first thoughts?
When did you start using the computer therapy? When did you finish?
How many times a week did you practise? What made you practise more? What made you practise less?
How long did each practice session last? What made you practise for longer? What made you practise for less time?
How often and for how long did [therapist name] and [volunteer name] suggest you should practise?
Can you tell me about using the computer therapy?
How often did you see [volunteer name] and how long for? Can you tell me about your relationship with [volunteer name]? What did you do during the visits?
How often did you see [therapist name] and how long for? Can you tell me about your relationship with [therapist name]? How did [therapist name and volunteer name] feel about the computer therapy?
Did anyone else help you with the computer therapy? What help did they provide?

Table 5.2. Summary of questions from the interview schedule

Visual analogue scale. Visual analogue scales have been used to enable PWA to answer questions about mobility (Della Sala et al, 2009) and mood (Hayley et al, 2015) with findings suggesting that they are valid tools for eliciting self-report. The first three questions from the

interview schedule were phrased to allow response using a visual analogue scale. The purpose of these questions was to provide contextual information allowing the author to have greater insight into the PWA's understanding of their own communication impairment and prior experiences of therapy in order to better understand their attitudes toward computer therapy practice. The visual analogue scales were developed in collaboration with the Big CACTUS Patient and Carer Advisory Group all of whom had experience of using or supporting use of the computer therapy (see appendix W for notes from the relevant meeting). The Advisory Group recommended that the scale should have one image of the concept in the middle of the page, with images (rather than text) at either end of an unmarked line to indicate the ends of the scale with the words "a lot" and "a little" spoken by the interviewer. The image selected to show "a lot" was a hand with the thumb and forefinger far apart and "a little" by the image of a hand with the thumb and forefinger close together (see figure 5.5). The marks made on the line by participants were measured using a ruler and have been collated on a single line with a 10 point scale added for ease of interpretation.

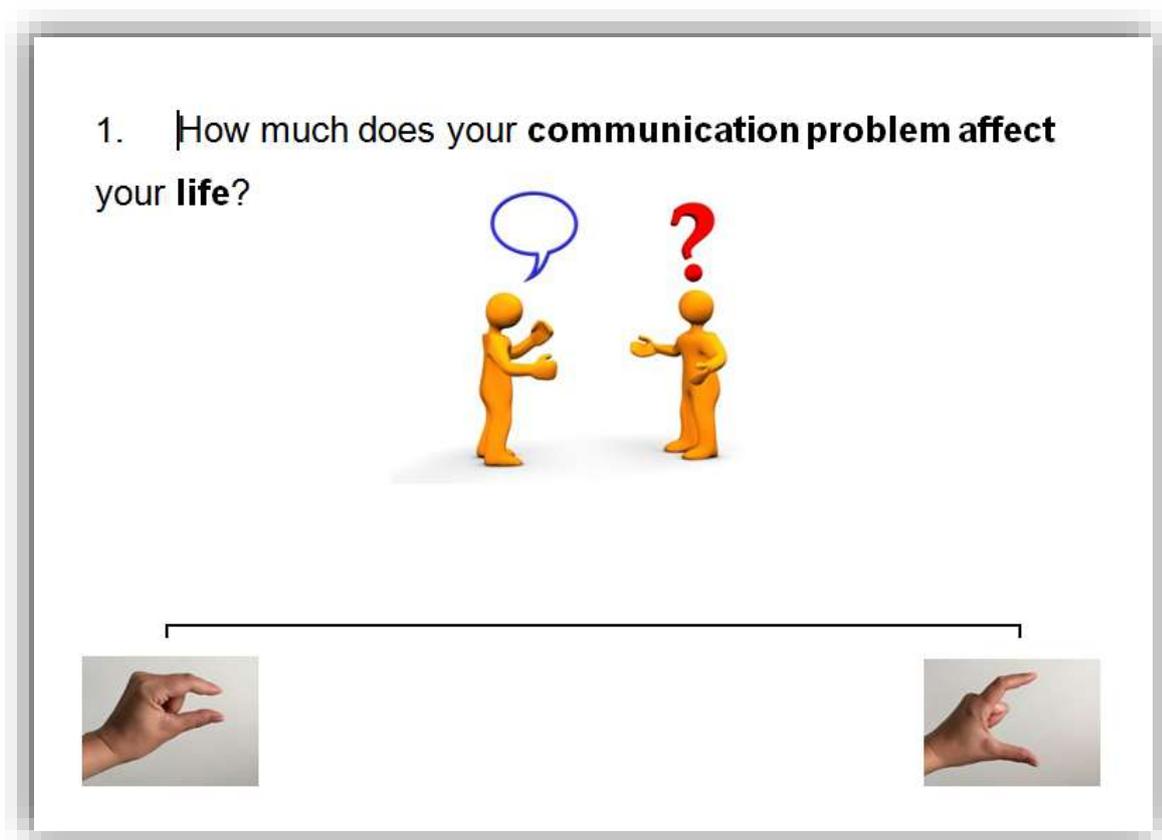


Figure 5.5. Example of visual analogue scale

Picture selection. When asked open-ended questions that were conceptually and grammatically simple, such as “What made you practice more?” participants were always given an opportunity to respond spontaneously. If a verbal response was not provided participants were shown a series of picture cards showing key concepts for the participant to select whether or not it reflected their perspective. Picture card development was informed by the findings of an earlier study exploring the acceptability of the same intervention (Palmer et al, 2013) and by the Big CACTUS Patient and Carer Advisory Group. The Advisory Group suggested a range of responses to the questions in the interview schedule and suggested images that could be used to depict the responses (see figure 5.6). The picture selection procedure involved the question being displayed on a large sheet of paper. The interviewer then read the question and the statements at the bottom of each picture card and the participant placed the card onto the sheet of paper if they agreed with the statement on the picture card. A photograph was taken of the selected picture cards. Once given a concrete example of a response to the question some participants were able to elaborate verbally.

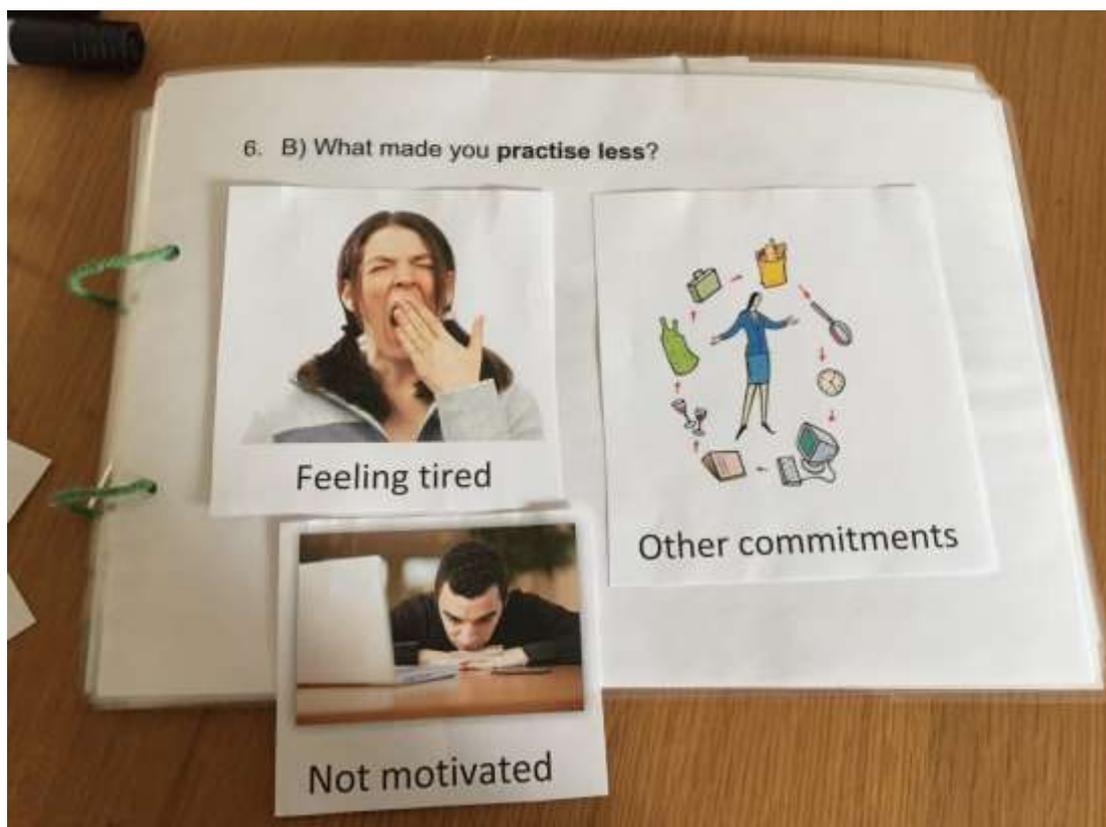


Figure 5.6. Example of picture selection cards used to facilitate response from participants with more severe communication impairment

Big CACTUS data for demographic and contextual information

Data collected for the Big CACTUS study, described in more detail in chapter one (page 37), was used to provide contextual information about the sample. Data included: age, gender, StepByStep usage data from key file, CAT naming objects score, CAT sentence comprehension score, personal vocabulary naming score and activity logs detailing the time the therapist and volunteer/assistant spent supporting the PWA.

Ethical approval

Ethical approval for the qualitative component of this study was obtained from the Research Ethics Committee in the School of Health and Related Research at the University of Sheffield (see appendix X).

Qualitative data analysis

The interviews were analysed using a six stage process of thematic analysis, which involves familiarisation, iteratively developing an initial coding framework, identifying themes, reviewing themes, naming and defining themes and writing up the findings (Braun & Clarke, 2006). Familiarisation was achieved through repeated reading of all transcripts. In-depth paper and pen based coding of a transcript from one high and one low adhering participant resulted in the development of an initial coding framework. One of the transcripts was also coded by a SLT independent of the study (LK) to enable exploration of different interpretations at an early stage and to provide insight into the interpretation of a therapist who works clinically with this population. The transcripts and combined initial coding framework were entered into NVivo 11 (QSR International, 2016). During the process of coding the transcripts in NVivo more codes were added and others were merged, grouped or renamed.

Once all transcripts had been coded the themes were reviewed by the author, her supervisors and an external qualitative data analysis expert (Dr Steven Ariss). During the review process it became apparent that two of the emergent higher order themes (barriers and facilitators) were not as useful as originally anticipated due to the multitude of cross-cutting sub-themes, which made the division appear artificial. As the sensitising frameworks underpinning the interviews the author returned to the COM-B system (Michie et al, 2011) and TDF domains (Cane et al, 2012), to explore whether these behaviour change theories could support the data interpretation phase. Therefore, a two-step inductive and deductive analysis process was used in which an initial thematic analysis was mapped on to an established model using a similar approach to that described by MacFarlane & O'Reilly-de

Brún (2012). No tensions arose during the mapping process as the data had a good fit with the COM-B system. The lower level codes (sub-themes) were mainly unchanged, however some were divided or combined where necessary to map onto the COM-B system. Higher order theme names were re-defined and the findings were written up (Braun & Clarke, 2006).

In order to be able to explore the similarities and differences between high and low adhering participants a feature of the NVivo software was used to categorise the transcripts as cases with different attributes (e.g. high vs low adhering participant). This enabled a matrix coding query to be run, which highlighted silences and allowed similarities and differences between the views of high and low adhering participants to be explored easily in order to identify patterns or features in how different groups of participants responded.

Sample size was determined by the concept of data saturation (Glaser & Strauss, 1965). Data saturation was deemed to have been reached when no new first or second level themes emerged from the analysis of two consecutive interview transcripts. This was achieved by the thirteenth interview. However, when the participant's characteristics were collated it became apparent none of the high adhering participants were female. This was reported back to the Big CACTUS Patient and Carer Advisory Group who felt that unless this was representative of the wider Big CACTUS sample it would be important to include the views of at least one high adhering female participant. A further interview was conducted with a high adhering female. No new themes emerged and data collection was deemed to be complete.

To provide additional contextual information about the qualitative interview participants, data from the Big CACTUS study, including demographic information, word-finding scores and activity log data, was tabulated for each individual.

5.4 PART A: QUALITATIVE RESULTS

Participants

The sample was identified from 51 PWA randomised to receive computer therapy in the Big CACTUS trial for which usage data from the StepByStep software had been received by September 2016. Invitations were sent to 22 PWA with the highest and lowest amounts of practice recorded, and/or their carer where appropriate. Of the 22 invitations sent out 14 PWA and/or carers agreed to take part, four were not interested and four could not be contacted. As such 14 interviews were conducted with 23 participants, including 11 PWA

and 12 informal carers. The mean interview length was 68 minutes (range 24 to 103 minutes).

The 14 interviews comprised nine with the PWA and their carer, three carer-only interviews and two patient-only interviews. Of the nine interviews including the PWA and their informal carer three were conducted jointly, thus generating a dyadic narrative, and six were conducted separately, thus generating two independent narratives from the same interview. Two of the carer-only interviews were conducted with informal carers of PWA who were not eligible as a result of severe comprehension problems. An additional carer-only interview was conducted with a carer whose husband was eligible, but declined to participate. All carer-only interviews were conducted with the carers of low adhering PWA.

Of the PWA participants that either took part or were referenced in carer-only interviews, ten participants were male and four participants were female. At the point at which the PWA entered the Big CACTUS study their mean age was 65 years old (range 48-85). The severity of the participant's word-finding impairment at baseline was determined by their score on the Comprehensive Aphasia Test (CAT; Swinburn et al, 2004) naming objects assessment. Both the low and high adhering groups included participants who were classified as mild (score 65-90%), moderate (score 35-64%) and severe (score 10-34%) (see table 5.3). With the exception of one participant that died prior to the six month outcome assessment and one participant who did not carry out any independent practice, all participants showed some improvement on the personal vocabulary naming test, in which they had to name the items they were practising on the StepByStep software (see table 5.3).

Participants were recruited as low or high adhering participants. In order to explore any differences between groups of participants they are identified after each quote as a low adherer (LA), high adherer (HA) or moderate adherer (MA). It was not intentional to recruit a moderate adherer. The participant was originally thought to be a high adherer, but following subsequent recruitment of much higher adherers, this participant's mean practice time of 34 hours 33 minutes fell in between the mean practice times for other high adherers (67 hours 21 minutes) and low adherers (13 hours 13 minutes) (see table 5.3).

Of the carer participants one was male and 11 were female. The average age of the carers at the time of the interview was 61 years old (range 46-76). The relationship of the carers to the PWA included: eight wives, one partner, one mother, one daughter and one son.

ID	Interview type	PWA Sex	PWA age at screening for trial	SBS 6 month usage data from key file	High, moderate, or low adherer	Severity of word-finding impairment (based on CAT naming objects score ¹)	CAT Sentence comprehension baseline score ²	Personal vocabulary naming score at baseline ³	Change in personal vocabulary naming score (0- 6 months)
R16/07	Patient & carer joint	Male	78	1h 45m	Low	Mild (36)	22	95	-3
R01/40	Patient & carer separate	Male	48	6h 35m	Low	Severe (14)	18	37	18
R19/19	Carer-only	Female	83	9h 28m	Low	Moderate (27)	8	37	N/A*
R13/21	Carer-only	Female	40	10h 36m	Low	Moderate (26)	10	65	15
R03/39	Patient & carer separate	Female	85	12h 39m	Low	Severe (11)	13	23	22
R15/01	Carer-only	Male	65	16h 56m	Low	Mild (36)	24	119	62
R06/01	Patient & carer separate	Male	54	34h 33m	Moderate	Mild (33)	26	58	57
R02/04	Patient-only	Female	77	58h 33m	High	Mild (36)	27	114	75
R10/37	Patient & carer separate	Male	70	60h 42m	High	Severe (14)	11	53	13
R15/20	Patient-only	Male	64	61h 58m	High	Moderate (22)	24	48	69
R15/37	Patient & carer Joint	Male	58	68h 55m	High	Severe (17)	15	31	35
R11/03	Patient & carer separate	Male	62	69h 1m	High	Mild (33)	21	172	26
R16/04	Patient & carer Joint	Male	75	72h 51m	High	Mild (38)	32	101	55
R10/02	Patient & carer separate	Male	54	79h 24m	High	Mild (31)	28	104	85

Table 5.3. Patient participant demographic information, StepByStep usage data, and scores on impairment based outcome measures used in the Big CACTUS study. ¹Possible scores on CAT: Naming Objects range from 0 to 48; ²Possible scores on CAT: Comprehension of Spoken Sentences range from 0 to 32; ³Possible scores on Personal Vocabulary Naming test range from 0 to 200; *Participant died prior to six month outcome measure.

Qualitative findings

Five themes emerged overall. The first two themes provide contextual information regarding participants' perception of their communication impairment and recovery, and their perceived amount of practice. The following three themes relate to participant's capability, opportunity and motivation to carry out aphasia computer therapy practice. Within the three main exploratory themes, relating to capability, opportunity and motivation, factors that were perceived to influence adherence (i.e. sub-themes) are shown in bold and listed in table 5.4.

Communication impairment and recovery: "he knows in his head, but he can't get it out"

Descriptions of participant's pre-stroke communication indicated that all participants were out-going individuals who valued communication prior to having their stroke. This was exemplified by one carer's description of her mother:

R03/39 carer: She was always sort of life and soul sort of thing and she always had an opinion and her opinion was always right! [laughter] Erm. She was a very friendly person she would talk to anybody. (LA)

Responses to the visual analogue scale question 'how much does your communication problem affect your life?' were varied, but interestingly the two low adhering participants and one moderate adhering participant felt their communication impairment had less impact on their life than the majority of high adhering participants (see figure 5.7).

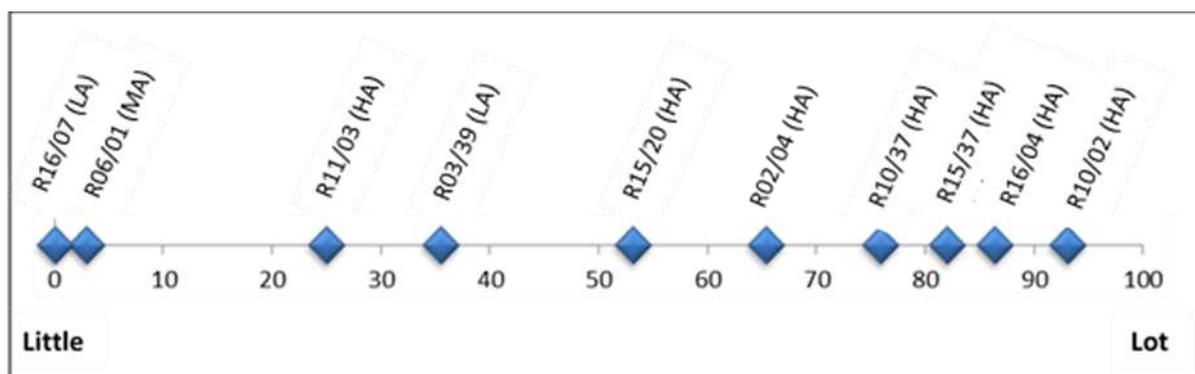


Figure 5.7. Patient participant responses to visual analogue scale illustrating individual perception of the impact their communication impairment has on their everyday life. NB R01/40 (LA) did not answer this question. Low adhering participants are not equally represented on the visual analogue scales as all three carer-only interviews involved the carers of low adhering participants.

All participants perceived some improvement in the PWA's communicative ability since their stroke occurred. Several participants commented on the slow speed of recovery, which had for some led to acceptance or at least normalisation of their impairment.

R11/03: I've improved since the stroke and hopefully it will improve as things go on. It's a long process. (HA)

Participant's provided varied reports of the amount of therapy they had received prior to starting the computer therapy, as indicated on the visual analogue scale in figure 5.8. Perceptions regarding the amount of therapy ranged from very little to more than they would have expected. There were no apparent differences between high and low adhering participants.

R19/19 carer: I think three hours isn't very good at all really to be honest with you, no matter what she thinks. I would have thought she should have got at least double that time and had a minimum set target of so many weeks. No matter how good or how bad they are. I mean three hours for someone who's been chatty all of their life I don't think that's a hell of a lot to aid them in anything. (LA)

R03/39 carer: Oh a few month, yeah she was-, she was gettin' it at the hospital and somebody came out just after she come out of hospital, she was still gettin' it. I was quite surprised how long they came round actually. (LA)

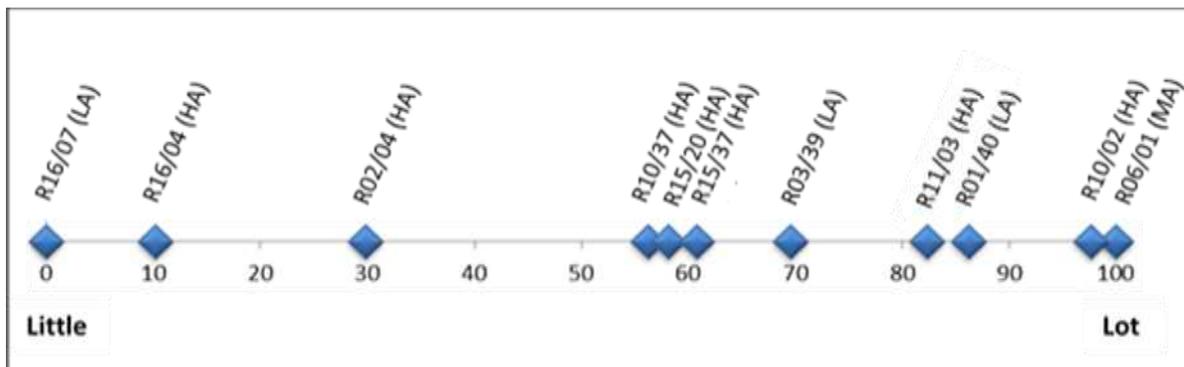


Figure 5.8. Patient participant responses to visual analogue scale regarding the amount of therapy they perceived themselves to have received prior to the computer therapy

Only one carer participant explicitly criticised the content of the therapy received prior to the computer therapy based on their perception that picture naming tasks were not useful to the PWA, but the same criticism was later made of the computer therapy.

R16/07 carer: You went to one [speech therapist], but she didn't actually-, you see, eh. [PWA] can-, when they turn over these pages, like with the computer, he doesn't-, sometimes he has difficulty with them, but mostly he knows these things. And I think he thought, 'well this is just words, do you know this isn't helping my speech at all, this is just pictures, which I know. I can answer all of those, but that is not helping me speak what I want to do'. So she did that and she did what she was supposed to do. I wouldn't say she was useless, cause she wasn't. (LA)

The third question presented as a visual analogue scale was 'how important is it to you that your communication problem improves?' (see figure 5.9). Despite several participants indicating that their communication impairment does not impact on their everyday lives, all participants' responses indicated it was moderately to very important that their communication impairment improved. No differences were apparent between the high and low adhering participants.

Interviewer: How important do you think it is to [PWA] that her communication problem improves?

R13/21 Carer: Oh 100% I would say. She finds that the-, apart from the physical things that you know-, the stroke, her arm and her leg not working very well. Well the arm not at all. The speech is the thing, her priority and she worries about the children growing up and she's like missing, you know, being part of their childhood. (LA)

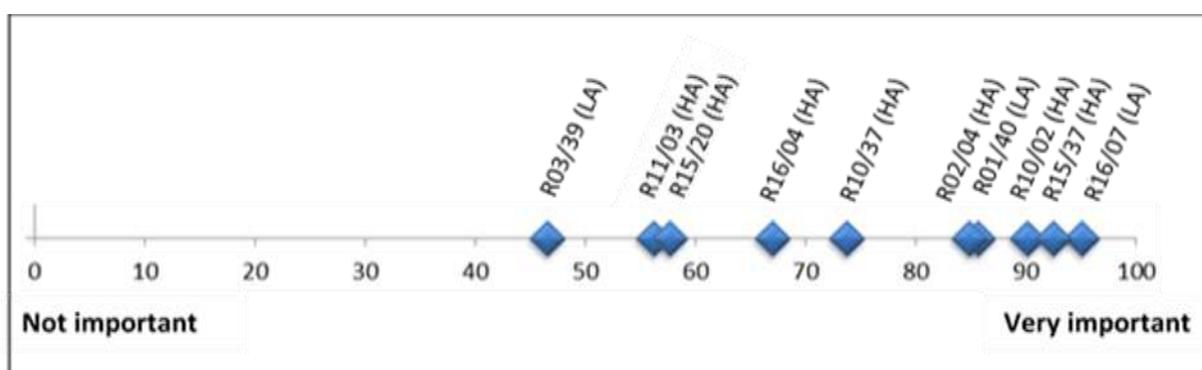


Figure 5.9. Patient participant responses to visual analogue scale regarding their perception of the importance they place on their communication impairment improving. NB R06/01 (MA) did not answer this question.

Despite nearly all of the participants placing a high value on their communication impairment improving, participant's expectations of recovery were variable both between and within participants. Low adhering PWA and their carers expressed more limited expectations of recovery than high adhering participants. Low expectations of potential recovery were attributed to their experience of recovery to date and also to information provided by healthcare professionals.

R15/01 carer: Some days I think he thinks that he can improve and other days he thinks 'This is it now', so that's where the frustration element comes in. (LA)

R15/01 carer: We have been told that, that six months was kind of like, you know the, the, as much improvement as you were going to get. (LA)

Behaviour: the perceived amount of practice

The amount of practice reported by participants was not as varied as one might have expected given a maximum variation sampling strategy was employed based on the amount of practice automatically recorded by the StepByStep software key file. The participant who practised the most according to the key file reported practising five days a week for 45 minutes.

R10/02: Every day. [...]I probably take the weekends off, shall we say, yeah. [...] I think it was about 45 minutes. (HA)

The carer of the PWA with the least practice recorded explained that he had not used the software without the therapy assistant present.

R16/07 carer: [therapy assistant] came and you'd get it out then, but otherwise no. (LA)

However, other low adhering participants reported practising at least two or three times a week for at least 20 minutes, which was not consistent with the total amount of practice time recorded. This was understandable in some instances where the participant stopped practising months before the six-month intervention was complete (they may have practised two or three times a week for the first few weeks or months). It is possible that in other cases it might be explained by social desirability bias (participants saying an amount of time they thought the interviewer would want to hear) or it could draw into question the reliability of the practice time data collected from the key file. However, one high adhering participant who described trying to trick the computer program to record extra practice felt the recording mechanism was accurate and couldn't be tricked to record a different amount of practice!

R11/03: I was trying it out reading the paper or somethin'. Okay. And it would either go back to zero or start again. Like if you have a 25 letter and I'm thinkin' we're coming up to me half hour here and I've done about 15 letters. Phew we're over 30 minutes, great, fantastic and I'd just pack it up. But if you pack it up the amount of time it's taken you to get those 15 letter that's taken off.⁴ Cause unless you've done the whole-, the proper-, 25 letters then it won't record you. If you've done 15 it won't record. So all that time you've spent on those 15 letters is taken off the total and you press the button back and yellow button. [...] So I had to do it properly. (HA)

Capability to use the computer therapy

Physically participants needed to be **able to use the computer therapy software**⁵. This was mainly described by low adhering participants with less prior computer experience. Participants described the vital role played by the assistants/volunteers in helping participants to **develop the skills** required to navigate the computer therapy.

R13/21 carer: I think just sorting out the programme, you know, how to get from one bit to the other and sometimes, you know, it was a bit difficult but I think when [assistant] came she sort of, you know, showed her how to get from one bit to the other. (LA)

Psychological capability was discussed in relation to participants' knowledge of the intervention, understanding of their own condition and the impact their cognitive impairment had on the amount of practice conducted. Participants **knowledge of the recommended amount of practice** they were expected to carry out was variable both in terms of the amount and frequency with which they recalled being recommended to practise, as well as the extent to which the amount was prescribed by the therapist/volunteer/assistant or a decision made by the PWA. Some participants described relatively strict guidelines from therapists regarding the recommended amount of practice. The recommended practice duration recalled by participants varied from 'five minutes' to 'one hour', but most participants recalled the amount specified in the treatment manual provided to therapists of 20-30 minutes. The recommended frequency of practice recalled by participants varied from 'everyday' to a 'few times a week' with no clustering of responses around the recommendation that practice should be carried out everyday as specified in the treatment

⁴ The participant is describing being half way through an exercise and reaching the half hour practice time, but the software will not record the time spent on an exercise unless it is completed.

⁵ Factors perceived to influence adherence (i.e. sub-themes) are shown in bold and listed in table 5.4.

manual. Low adherers more often felt the decision regarding whether or not to practise was based on personal preferences and lifestyle factors.

R15/01 carer: She said obviously don't let it take over your life but she really sort of left it to us to work out fitting into the lifestyle as to how much he should or shouldn't do. (LA)

Aphasia is a complex condition and participants had varying levels of **understanding or knowledge about their own condition**. The participant who practised least reported that they could name all of the vocabulary available to practise on the computer therapy. However, the personal vocabulary naming assessment demonstrated that R16/07 was able to name less than fifty percent of the same items at baseline and six months (see table 5.3). The participant was therefore demonstrating a lack of awareness or potentially denial of their own communication impairment and it was therefore understandable that the same participant also found it hard to understand the purpose of the software or the possibility of improvement. Some of the other low adhering participants expressed similar thoughts.

R16/07: Just doing them words. When you have the computer out you had to say what it was and what it weren't and I knew exactly what it was anyway.

Interviewer: Was that matching the pictures?

R16/07: Yeah. It wasn't making any good to me anyway, cause I knew exactly what they were cause they're already in there. I could say all of these things. (LA)

R03/39: I didn't need it. I needn't it at all... (LA)

In contrast, having more knowledge and understanding of aphasia, as well as having more insight into the impact their communication impairment had on their lives was a motivating factor for those participants who were able to describe how their impairment affected their everyday life.

Interviewer: What do you think made you, kind of, do so much practice what, what spurred you on?

R10/02: I realise my language was letting me down see. (HA)

Some participants' perceived practice to have been limited by stroke related **cognitive impairments**, such as memory problems and problems with concentration, as well as **fatigue**.

R03/39: I used to do everything, but I forget things every now. (LA)

R13/21 carer: She can't concentrate on more than one thing at once, if you know what I mean and children sometimes can be, you know, in the background and not even being noisy, but you are conscious of them, aren't you? (LA)

R02/04: It, I can't, er, do it after I'm tired. (HA)

Another carer described how impaired cognitive functioning prevented independent practice meaning someone had to be available to help him to use the computer therapy, thus demonstrating an association between reduced capability and reduced opportunity for practice.

R01/40 carer: He couldn't quite work everything out on his own so it was always with somebody. (LA)

Some participants described strategies they had found to overcome the impact of cognitive impairment, such as selecting a time of day to practise when they were most alert.

R13/21 carer: In the morning if possible, when she wasn't so tired, you know, after breakfast or after a meal or a snack or something because she tends to get more tired if she's not eaten or had something to drink recently. (LA)

Having the opportunity to practise: external influences and technological issues

The physical aspects of opportunity predominantly related to the StepByStep software and the hardware to run it on, as well as the support provided by SLTs/volunteers/assistants.

Computer therapy software problems were described as a significant barrier to practice. In particular problems with the voice recognition component of the software, which provided feedback on the performance of the participant.

R10/02 carer: Yeah, it was mainly the technical side I think. Um, the, um, as [PWA] progressed he got, he was using the voice recognition. So he, he was, a picture would come up and he'd say 'oh, this is [nephew]', um, but it took, it was taking a while for the voice recognition on the microphone to log with the computer, you know, and the computer go 'ping', tick, you know. Um, so [PWA] would, would have to say it two, three, four times and that was then stopping the computer and that, that became quite, er, frustrating for him and then sometimes it, it would be just seize up because it, it was trying to do too many, you know, things... (HA)

Whilst nearly all of the participants described the issues with voice recognition as frustrating, some participants continued to practise with work arounds suggested by therapists including being told to *skip* that aspect of the computer therapy or in some cases the therapist *hid* the voice recognition component. However, for some participants, particularly those who perceived a need for reinforcement, skipping the voice recognition step was not a satisfactory solution and this was a factor in a reduction in practice for these participants.

R15/01 carer: He sort of tried to skip it [picture naming with voice recognition step] but I think to him it didn't really seem to make too much sense when he had skipped it cause, as I say, he really needed to have that reinforcement to come back to him to say that he had got it right so he could move on. I mean I'm not blaming the computer, don't get me wrong, but I think it was one of the factors that, you know, made him sort of think, oh well, you know...we will do less and less time at it. (LA)

The other issues with the software reported by participants related to the stability of the software including the software crashing and not being able to move between the different sections or exercises within the software.

R03/39 carer: I think what put her off as well was all the hassle we had when things kept going wrong with the program and it kept crashing or whatever. (LA)

R03/39 carer: And it wouldn't go onto the next thing or it would go back to the one that she'd just done or we couldn't get into the right section. (LA)

Some of the issues with the stability of the software related to the fact that the software was an early release of version 5 of the StepByStep software. Several updates were available during the time participants were using the software, and participants described performance improving after updates.

R10/37 carer: Yeah I mean the issues were there and, as I say, they solved them. I mean it was-, when [PWA name] first started the program I think it was right at the very beginning and I don't think they had perfected the program. I don't think it was perfect to start with. I think it's got better and we've had a couple of updates on it since. (HA)

A smaller number of participants had **computer hardware problems** which prevented access to the software. Most of the problems described were the result of using outdated (e.g. slow operating system or operating system not compatible with software) or unfamiliar (e.g. participant having to learn to navigate a new computer system) hardware. The process of determining whether blame for the problems lay with the technology itself or the way in

which the participant was using it demonstrated links between having the opportunity to use the computer therapy and the participants actual or perceived capability to do so.

Interviewer: So my next question was what made her practise less?

R03/39 carer: I think cause of the problems with the laptop. (LA)

R03/39 carer: So I never knew whether that was my fault-, whether it was our fault or the computers fault. I mean, I know she did swap it over at one time and I said, 'can you not get us a new one?', 'No we're not allowed new ones', she said, 'it's all old ones'. (LA)

Participants described several **features of the software that facilitated more practice**. The *personalisation of vocabulary* within the computer therapy was perceived to inspire more practice.

R15/37 carer: The fact that you could choose your words, you chose the words you wanted, was that? That was something that made you practice more because they were your words and not just on a computer they were the words you wanted to say.

R15/37: Yes. (HA)

Several participants also thought that using the therapy in their home environment facilitated more practice and also enabled them to re-visit forgotten aspects in their own time.

R01/40 carer: Yeah definitely good that you didn't have to go anywhere, yeah. (LA)

R15/01 carer: You know, he didn't need to say 'Oh that's done and dusted I have to move on' he could go back over something if he thought 'I don't quite remember that today 'so that was two plusses definitely, I think. (LA)

High adhering participants who were able to use the computer therapy on their own relished having an independent activity and enjoyed having something to occupy their time when their informal carer was busy.

Interviewer: You like being able to get on with it on your own?

R10/37: Oh yes. I get on with it, away-, leave me on my own. (HA)

Several participants made comparisons between computer aphasia therapy and face-to-face word-finding therapy, in which they were either comparable or favoured the computer therapy, but one participant felt that although the exercises were similar the mode of presentation was not to her mother's liking.

R03/39 Carer: And then [lead therapist name] came with the computer and it was similar, similar type stuff, except she didn't like the computer! (LA)

Barriers to practice identified by participants included: illness, having other commitments and engaging in alternative therapeutic activities. *Periods of illness* prevented participants from being able to carry out computer therapy practice.

R01/40 carer: He only used it for about three months and then he became very ill. (LA)

One of the foremost reasons participants provided for not adhering to the recommended practice time was their *other commitments* that took priority over doing the computer therapy. The other commitments described by participants were varied, but some examples included going to appointments, going on holiday, receiving physical care or caring for a family member.

R11/03: The only time days off was cause I was going on a cruise. (HA)

R19/19 carer: Mum's time was always dictated by the carers and the medicine she had to take and all that. (LA)

R15/01 carer: And as I say when I broke my wrist, he got rather distracted by me as opposed to anything else and then he didn't really go back to it. (LA)

Many of the other commitments participants described were perceived to be unavoidable, however some low adhering participants acknowledged that the computer therapy rarely took priority over other activities.

R15/01: There were other things that he wanted to do and which took over. (LA)

Several carer participants described the PWA engaging in alternative therapeutic activities, often suggested or led by the carer using word games, activities suggested by speech therapists (e.g. naming picture cards) or educational computer programs designed for children. The activities described had been engaged in prior to and during the time that the aphasia computer therapy was available to the PWA. Carers of low adhering participants described encouraging the participant to engage in these alternative activities when the PWA did not want to use a computer.

R19/19 carer: We done a few little things ourselves off the internet, like we'd have stuff like, for want of a better word, like food and transport and animals and what-have-you. So if she didn't want to go on the computer, which we always tried to get

her on the computer at least a half hour every day, we bring out like our own little flip sheets. (LA)

Almost all participants', including those with limited expressive communication (using the picture selection task), expressed that having help and **support available** from a therapy assistant/volunteer enabled more practice. One carer participant reported that their spouse received minimal input from a volunteer/assistant and felt that they would have been more motivated to practise if regular external support had been available.

Interviewer: So some people thought that having help made them practice more, was that the case for you?

R01/40: Yeah. Help. (LA)

R15/01 carer: It would probably have kept his motivation a little higher in the respect that people would come round, not just to sort of click a memory stick in and take out a reading and see what's been done. I think if someone had come and sat with him, you know, maybe every six weeks, or a month or something like that, you know, somebody who's a professional, not me. (LA)

Some participants, particularly those with more significant communication impairment expressed a need for more help and support.

Interviewer: You wanted more support with using the computer?

R01/40: Yeah. (LA)

This was reiterated by the carer who blamed herself to some extent for the limited amount of practice completed by the PWA. The feeling that the carer had not provided enough input was only described by participants with more significant communication impairments (indicated by lower scores on CAT naming or sentence comprehension tests, see table 5.3) that prevented them from using the computer independently.

Interviewer: So how many times a week did [patient name] practice, obviously whilst he had the-?

R01/40 carer: Not as much as he should have to be totally honest which is half my fault. (LA)

A small number of low adhering participants did not perceive the supporter visits to be helpful, but no specific criticisms of the support were provided.

Interviewer: So you pretty much only practised when she came out to help you. And was it-, did you find that useful? Did you find her coming out useful?

R16/07: I don't think it did anything. (LA)

As well as having the physical opportunity to carry out aphasia computer therapy practice, participants also described the social opportunity afforded by their interactions with others. Several carer participants described the importance of having **external support** from a speech and language therapist, assistant/volunteer or more removed family member. It was perceived, particularly by the primary informal carers, that support from an external agent was more beneficial and allowed the PWA to engage more fully.

R16/04 carer: Yeah the prompting and the people that aren't me telling him because he doesn't listen to me in the same way and I understand, why would he? But he is better if it is people outside, it would have been better. (HA)

The added benefit of an external supporter was that their visits created a **social pressure** to carry out more practice. Participants described upcoming visits triggering a sense of obligation to practise and the desire to please the supporter.

Interviewer: And what made you practise for that long?

R10/37: Erm. We did it because we'd been asked to do it. (HA)

R16/04 carer: He likes to please, so he would have, I think he would have probably done that [continued to practise] still, yeah. (HA)

Motivation: beliefs, goals and intentions versus personality, emotions, habit and reinforcement

In addition to participant's actual physical or psychological capability to carry out aphasia computer therapy, participants also described their **beliefs about their own capability** to do the therapy (i.e. self-efficacy). Concerns about capability were primarily expressed by low adhering participants. Lack of self-belief in their ability to carry out independent practice often stemmed from their lack of prior computer experience. For one participant this resulted in an overwhelming fear of breaking the computer.

R16/07: Well when they said that I could use a computer I thought, 'I won't be able to do that, how am I going to do that?' [...] I mean-, we've never had a computer. (LA)

R19/19 carer: As I say if she didn't buy it she didn't want to use it in case she broke it and I think that's a lot with the older generation, they are too frightened in case they break something and it isn't theirs. That's what we used to tell [therapist] when she was here, 'look she won't use it unless someone else is here'. (LA)

Contrastingly, some participants described having a strong belief in their own ability to use the computer therapy prior to commencing therapy irrespective of their familiarity with computers. Only high adhering participants described this high sense of self-belief.

R11/03: An' I thought I'm not too much into computers, but it's easy innit? Honestly it's easy, just click it and job done. So I thought perhaps I can handle that for half an hour, I can handle that. Most of the time I was sitting on my backside anyway, you know, for half an hour I can handle that. (HA)

The concept of self-belief also underpinned a feedback loop described by a participant who explained that the vocabulary topics and exercises that she liked were more motivating to practise because they were the ones she performed well on, thus demonstrating that the positive task performance reinforced self-belief in her ability to complete the task and consequently motivated more practice.

Interviewer: What made you practise more?

R02/04: I liked it. And erm-, the erm-, the animals I liked and erm-, I liked the typing.

Interviewer: Yeah.

R02/04: Cause I'm good at it! [laughter] (HA)

As well as belief in their own capability, participants also described their **beliefs about the consequences** of the intervention. Participant's descriptions of their expectations prior to commencing aphasia computer therapy were varied, but all participants expressed some desire for recovery. Many participants described a general desire for any therapeutic opportunity available and most of the high adhering participants were already pursuing other activities for their perceived benefits, such as attending community stroke groups.

R02/04: I wanted to do anything to help my speech and, er, to help me go along with my life. (HA)

Contrastingly, a carer of one of the low adhering PWA described the participant's pessimism and lack of belief that the intervention could produce a beneficial outcome.

R16/07 carer: I think you didn't give it a chance, but you just said, 'what's this doing to help me?' (LA)

Participant's descriptions of carrying out continued regular practice responded to an underlying expectation that regular practice would result in an improvement in their performance and overall recovery from their aphasia.

R06/01: I will do it and do it and do it until I get it right. (MA)

R11/03: I kept on doing it until I got right cause in my brain I wanted it sorted out. (HA)

The expectation of improvement may have resulted from the fact that most participants perceived that the supporters believed in the effectiveness of the aphasia computer therapy and thought it would be a good opportunity for the PWA.

R06/01 carer: I got the impression she [therapist] believed in it, I think, yeah. Cause if I hadn't got that impression I wouldn't have continued with it, so yeah, yeah. (MA)

All of the high adhering and some of the low adhering PWA and their carers perceived some improvement in communication that they attributed to use of the aphasia computer therapy. For some participants this improvement related only to improved word-finding, but for others they perceived that this had generalised into an improvement in everyday conversation.

R10/37 carer: Yeah definitely saw an improvement.

Interviewer: And did that alter your relationship at all, did that make conversation easier?

R10/37 carer: No I think that was probably the same. (HA)

R15/37 carer: I think you could name those things easier than before. I think just learning words like that has a knock on effect in everyday speech. (HA)

High adhering participants and their carers, who typically had a good understanding of their impairment more frequently described their distal **goals** (i.e. long-term) in terms of what they hoped to achieve from carrying out regular practice. Proximal goals (i.e. short-term) were perceived to motivate longer individual practice sessions.

R16/04: I wanted to do it.

R16/04 carer: You wanted to be able to speak properly, didn't you?

R16/04: Yeah. (HA)

R15/01 carer: Occasionally he would go over the twenty minutes, but it's only if he thought to himself 'Well, I want to get here, I want to achieve this goal'. So he was setting himself little goals along the way. (LA)

Some participants described goals having been set for them by SLT or assistants/volunteers which they also found to be motivating, particularly when they were combined with feedback from the computer therapy software.

R11/03: She [the assistant] would go through a few of them and see how I was doing and at one stage [therapist] said to her if I want to move on I've gotta get above 90%. And I was getting almost 90% for most of them and that's sort of inspired me to crack on with it. (HA)

For one low adhering participant there appeared to be a mismatch between the goal of the patient (improved conversation) and carer and the perceived goal of the intervention (naming more words).

R16/07 carer: He could say donkey, horse and things like that and name them. But to me that is not what-, he needed conversation, not particular things you need. (LA)

Participants, particularly carers described changes in the **stability of the PWA's intention** to practise. The instability in intention could be explained by the Transtheoretical (Stages of Change) Model in which individuals move between levels of motivational readiness: pre-contemplation, contemplation, preparation, action, and maintenance/relapse (Prochaska et al, 2005). Movement between the stages (both backward and forward) is accounted for by self-efficacy and weighing up pros and cons. Where a change in motivational readiness was described it was typically a decline in practice over time as initial excitement or interest reduced combined with other influences, such as lifestyle changes or a reduced belief in the consequences, particularly where the expectations for recovery were potentially unrealistic.

R15/01 carer: I think it's like a lot of things in life, isn't it, you know, you start off, you are very highly motivated and then when you are kind of left to your own devices, it starts to peter out, so I didn't think it would happen but it obviously did and you know, when I noticed he wasn't going in and doing the computer therapy any more, I sort of said to him about it and that's when I thought well... well he actually said, 'No I don't want to do it any more'. (LA)

R15/01 carer: It did seem as though the motivation was still there but the actual, how shall I say it, the discipline had disappeared. (LA)

Interviewer: What do you think made her practise more to start with?

R03/39 carer: She thought it was goin' to be a miracle cure. (LA)

In some instances there were **differing intentions between PWA and their informal carer**. Carers of low adhering participants sometimes described different levels of intent between

themselves and the PWA with the carer wanting them to carry out more practice. The social pressure described by some of the carers encouraged PWA to agree to do the computer therapy (i.e. preparation), but did not result in regular practice (i.e. action) and for one PWA-carer dyad the mismatch in intent resulted in conflict, potentially indicating the importance of the PWA expressing their own interest in engaging with aphasia computer therapy.

R19/19 carer: Cause we [two primary carers] said, 'Yes we'll do it', and [therapist] said, 'Well look here's my number, have a talk with your mother she doesn't look overly impressed.' (LA)

R19/19 carer: Now and again I think she found it in herself like, 'oh I don't want to do this today', and it would cause-, well we might have a bit of a row. I'd say, 'come on mam you've gotta do this, you've gotta', and she would, 'no', she didn't want to know. (LA)

In contrast, the wife of one high adhering participant who admitted to have becoming obsessed with the computer aphasia therapy described wanting the PWA to practise less, in part due to the frustrations caused by problems with the voice recognition.

R11/03: She [carer] sort of said "you're over doing it. It's not actually possessing you, but you're actually-." I think basically my wife got a bit fed up of it cause I'd say the word and she'd be sitting there and I'd say the word and I've gotta say it for an hour. You say to 'em "Birmingham". No it didn't work that time gotta try again. "Birmingham" no. (HA)

Other motivational factors can be described as automatic as they are based on emotions and impulses. Carer participants, particularly those of low adhering PWA, perceived that the **emotions** experienced by the PWA, particularly their mood and attitude on each individual day, played a significant role in their decision to practise.

Interviewer: And what made your mum practise more?

R19/19 carer: I think if she was having a really good day, you know how sometimes you can wake up yourself and you have a bad-, you know down, but when she had a good day you could see she was happier and she was just 'bom' she'd go through it no problem. (LA)

As a factor for enabling practice **personality** was only described by moderate and high adhering participants. Personality factors perceived to be associated with practising more included determination and perfectionism.

Interviewer: Is there anything that you think made [PWA] practise more with the computer therapy?

R06/01 carer: His personality, because he's so determined and so-, if he sets his mind to something he wants to do it and wants to do it really well. (MA)

Many of the high adhering participants described developing a routine pattern of practice which resulted in a **habit** being formed thus increasing the automaticity of the behaviour.

The routine either involved doing it every day at the same time or having a regular trigger, for example PWA's spouse watching a television drama in the evening or adopting a Monday to Friday practice pattern imitating the working week.

R11/03: So I made it my routine to do it first thing in the morning before I had me breakfast. (HA)

R10/37: I just thought I was doing a job and I just did it like a job. So I did it five days, seven days and then I'm back. (HA)

One participant described himself as having become **obsessed** with the aphasia computer therapy. This impulse, which appears to have developed as a result of a strong desire to obtain positive feedback from the therapy program, resulted in a lot of practice, but to the detriment of other aspects of his life, such as sleep.

R11/03: I've even been obsessed and I can't sleep and I'm sitting in bed and I thought "bugger it!" so I'd get up and do it and once you've done it then you think now what am I gonna do?' I've got up early to do it. (HA)

The StepByStep software provides two types of **reinforcement**: feedback about the amount of practice time completed and feedback on word-finding ability. Participants found feedback about practice time on the colour coded calendar (yellow = some practice, but less than twenty minutes; green = more than twenty minutes practice) motivated them to practise for longer. One participant who found this form of feedback particularly rewarding also described that it encouraged active practice because the computer therapy did not record time spent idle.

R03/39 carer: Yeah I think, yeah, well I says, 'Mam that's gotta change colour you know, if it doesn't change colour you haven't done enough', [imitation of mother with begrudging tone] 'alright'. [laughter] (LA)

R11/03: If it comes down and it's got like a yellow thing that's no good, that's about twenty minutes or so, that's no good I've got to get a green. So you've got to be at

least half an hour, maybe a little bit over the top for it to actually transmit. And you can't take any-, in my experience you can't take-, well we've done three or four and then we'll stop and read the paper cause it kicks out. There's loads of ways round it, take it from me I've tried most of them. So you've gotta do a full thirty minutes. (HA)

Participants valued the feedback the StepByStep software provided on naming performance when the voice recognition function was available and on the spelling tasks in the using 'writing to cue naming' exercise. In confirmatory responses during the picture selection task, participants felt seeing the results, trying to do better than last time and trying to achieve 100% were factors that motivated them to carry out more practice. Feedback on performance was perceived to be one reason why computer therapy could be more motivating than paper based exercises provided by SLTs.

R10/02 Carer: He wasn't that motivated until she [SLT] would come the next time and then he'd go, 'oh, I've got to do my exercises', whereas the computer was something very real that he could see and, and perform against, or with on a day by day basis and that really suited [PWA]'s, um, learning, or the way he, you know, works. [...] He could see his performance, he could see he was making improvement. He had a step by step, 'ooo I've, I've achieved number three today, ooo I'm gonna do number four'. You know so, so for [PWA] it was very motivating and because it was so visual, I think it really helped him. (HA)

Summary of results

The factors associated with adherence were assimilated within the COM-B system (Michie et al, 2011), using the TDF domains (Cane et al, 2012) where appropriate. This provided a useful structure enabling discussion of whether individual factors were associated with more or less practice or both; this has been presented using arrows in the table summarising the findings (table 5.4).

Capability	Opportunity	Motivation
<p>Physical</p> <ul style="list-style-type: none"> • ↓ Ability to use computer therapy software • ↑ Assistants/volunteers help PWA to develop the skills required to use the computer therapy 	<p>Physical</p> <ul style="list-style-type: none"> • Computer therapy software problems (↓issues with voice recognition; ↓stability of the software; ↑stability of the software was improved via software updates) • ↓Computer hardware problems • Features of the software that facilitated more practice (↑ personalisation of vocabulary; ↑therapy in home environment; ↑ independence HA only) • Barriers to practice (↓periods of illness; ↓other commitments; ↓engaging in alternative therapeutic activities) • Availability of support (↑more input from supporters; ↓supporter visits not helpful LA only; ↑informal carers of participants who could not use computer therapy independently) 	<p>Reflective</p> <ul style="list-style-type: none"> • Beliefs about capability (↓capability concerns often based on lack of prior computer experience; ↑high self-efficacy HA only) • Beliefs about consequences (↑expectation of anticipated outcome influenced by supporters; ↓pessimism) • Goals (↑distal goal associated with regular practice; ↑proximal goal associated with longer practice session; ↓mismatch between personal goal and intended outcome of computer therapy) • Stability of intentions (↓ LA described decline over time) • Differing intention between PWA and carer (↓carer more motivated than PWA; ↑ PWA obsessed carer encouraging less practice)
<p>Psychological</p> <ul style="list-style-type: none"> • ↑ Knowledge of recommended practice time • ↓Understanding/knowledge of own condition • Cognitive impairment and fatigue (↓forgetting; ↓concentration problems; ↓fatigue; ↑strategies to overcome e.g. practice certain times of day) 	<p>Social</p> <ul style="list-style-type: none"> • ↑ External support (importance of input from SLT or volunteer/assistant) • ↑ Social pressure (caused by impending visit from supporter) 	<p>Automatic</p> <ul style="list-style-type: none"> • Emotion (↓low mood or negative attitude on given day) • Personality (↑determined/perfectionist) • Habit (↑routine pattern of practice) • ↑Obsession (impulse to practice detrimental to other activities) • Reinforcement (↑feedback about practice time; ↑feedback about performance)

Table 5.4. Factors associated with adherence to aphasia computer therapy categorised into themes using the COM-B system (↓ = factor associated with less practice; ↑ = factor associated with more practice; ↓↑ = factor associated both with more and less practice).

Qualitative summary/discussion

Participants described their communication impairment and expectations of recovery in detail and much importance was attached to improving the PWA's communication impairment. The perceived impact of the communication impairment on their life was varied as were participant's expectations of recovery, however low adhering participants and their carers more often expressed more limited expectations of recovery. The perceived amount of practice reported by participants were more similar than one might have expected given a maximum variation sampling strategy based on adherence was employed. This could draw into question whether the distinction between low and high adherers was artificially created by the author's choice to label the participants as such. Whilst this was true to some extent the distinction allowed the author to identify themes arising from different groups which provided additional indication of whether the factors identified were barriers or facilitators of adherence. Participants descriptions of the amount and frequency of practice sessions recommended by supporters was more variable, with low adhering participants commonly perceiving the decision regarding practice time to be based on personal preference and lifestyle factors.

Participant's physical ability to use the computer therapy was perceived to be associated with more practice and development of the skills to use the computer therapy was aided by support from assistants/volunteers. Psychological capability to carry out more practice was influenced by PWA's knowledge of the recommended practice time and understanding of their own condition, with cognitive impairment and fatigue perceived to limit the amount of practice carried out.

The physical opportunity to practise was reduced by computer software (particularly the voice recognition) and hardware problems, as well as other barriers including illness, having other commitments and engaging in alternative therapeutic activities. Certain features of the intervention including the personalisation of the words PWA were practising and the therapy being available in the home were factors associated with more practice. Availability of support from therapists and assistants/volunteers provided both physical and social opportunity for practice. In particular, the presence of external supporters was perceived to enable more practice as they created a social pressure to carry out more practice that the support of an informal carer did not provide.

Motivation was the theme in which there was the most difference between the experiences and views of low and high adhering participants, with high adhering participants better able to describe relevant goals, express belief in their own ability to use the computer therapy and belief that the computer therapy would improve their communication. In contrast, low

adhering participants more often described their intention to practise declining over time and differing intent between the carer and the PWA, which might explain why some PWA with little intention of practising initially agreed to engage in the computer therapy. Automatic motivational factors related to personality traits (i.e. perfectionism) and habits (i.e. practice became part of routine), both of which were described by high adhering participants. One participant also highlighted obsession as a factor leading to more practice, but this impulse to practise was detrimental to the participant's everyday life. Reinforcement in the form of feedback about practice time was perceived to motivate more practice, whereas feedback about performance was only beneficial on occasion as the feedback was sometimes incorrect when based on voice recognition. Low mood and negative attitudes were highlighted as barriers to practise by the carers of low adhering participants.

5.5 PART B: QUANTITATIVE METHOD

Design

The second part of this chapter describes a quantitative exploration of the factors associated with adherence to aphasia computer therapy. Modelling of the relationship between adherence to computer therapy practice and the demographic, clinical and intervention variables collected as part of the Big CACTUS trial. Secondary analysis of data collected from RCTs have been found to be a useful method for exploring intervention delivery and establishing whether an intervention could be more beneficial if it were targeted at those participants best able to engage with it (Rothwell, 2005).

Participants

Data from all participants randomised to receive the computer therapy intervention in the Big CACTUS trial were included in this analysis. For information about the Big CACTUS study eligibility criteria see chapter one (page 38).

Procedure and ethical approval

Data was extracted from the Big CACTUS trial database with support from a data manager in the Clinical Trials Research Unit. Ethical approval for this aspect of the study was sought from Leeds West Research Ethics Committee (REC; appendix F) and the Scottish A REC (appendix G) through an amendment to the protocol (version 4.0, 17 July 2015) for the main Big CACTUS trial (ISRCTN: 68798818).

Measures

As previously described (page 24) the CFIF proposes that adherence incorporates the four elements of coverage, frequency, duration and content (Carroll et al, 2007). The StepByStep approach to aphasia computer therapy also has four components: 1) StepByStep software, 2) therapy set-up: tailoring and personalisation, 3) regular independent practice, and 4) supporting and monitoring use (chapter three, page 81). With four elements of adherence and four components of the therapy there are multiple measures of adherence that could have informed this analysis. However, the total amount or 'dose' of computer therapy practice completed by the PWA was selected as the dependent variable for the purpose of this analysis as it is the measure of adherence most frequently described in the stroke rehabilitation (see literature review, chapter two) and aphasia (Brogan et al, 2019) literature. Total practice time (hours) completed by participants was recorded on an electronic file (called a key file) by the StepByStep computer therapy program. The key file data was

exported from the participant's device by the local Big CACTUS SLT during their last contact with the participant and returned to the central team.

Data was collected as part of the Big CACTUS trial by SLTs during visits to the participants home where they supported them to answer a series of questions and carried out language assessments (for more information see Palmer et al, in press) and from therapist documentation of the time they and others spent supporting the participant. Independent variables have been divided into three categories: demographic, clinical and intervention. The variables are presented in table 5.5 with details of how the variables were measured described in turn below.

Demographic variables	Clinical variables	Intervention variables
Gender	Time post-stroke	Device ownership
Age	Number of strokes	Type of device used
Presence of informal carer	Type of aphasia	Length of computer therapy access
Support group attendance	Evidence of apraxia of speech accompanying aphasia	Therapist time supporting participant
Internet access in home	Word-finding ability (severity)	Therapy assistant/volunteer time supporting participant
Site	Comprehension ability (severity)	Therapist time supporting therapy assistant/volunteer
	Self-reported communication related social participation	
	In receipt of care for communication difficulties	

Table 5.5. Independent variables divided into demographic, clinical and intervention groups

Demographic variables included: gender (male or female); age (≤ 55 , 56-65, 66-75, ≥ 76 years old); presence of an informal carer (yes or no; an informal carer referred to a friend or family member); whether or not they had attended a support group in the three months prior to entering the trial; whether or not participants had internet access in their home and which site they were based at (recruiting Speech and Language Therapy department).

Clinical variables included: time post-stroke (years); number of strokes; type of aphasia (anomic, non-fluent, mixed non-fluent or fluent determined by therapists clinical judgement); evidence of apraxia of speech (yes/no based on therapists clinical judgement); severity of word-finding impairment (assessed by Naming Objects sub-test of the Comprehensive Aphasia Test (CAT; Swinburn et al, 2004)); comprehension ability (assessed by Comprehension of Spoken Sentences sub-test of the CAT); participants' own perception of communication related social participation and quality of life (assessed by Communication Outcome after Stroke (COAST; Long et al, 2008) score) and whether or not they had received care for communication difficulties in the three months prior to entering the trial.

Intervention variables included: the type of device used (tablet, laptop or desktop computer); who the device was owned by (owned by participant or loaned to participant) and the length of computer therapy access (days) as recorded by the therapist. Activity logs completed by the therapists recorded: therapist time supporting the participant (minutes; this included providing technical support and monitoring the participants progress, directly or indirectly, and making adaptations to the therapy exercises; initial tailoring time not included); therapy assistant/volunteer time supporting participant (minutes; this included time spent setting-up/adjusting the computer or microphone, encouraging/motivating use of the computer therapy, providing assistance with using the software, and conversations to practice using the words they were learning with the software in context); and therapist time spent with the therapy assistant/volunteer (minutes; including providing training, supporting the assistant/volunteer, providing technical support or monitoring the feedback form).

All data were collected by therapists working on the Big CACTUS study and entered on the Big CACTUS study database. All demographic and clinical variables were collected prior to the participant's randomisation in the Big CACTUS trial. All intervention variables were time-dependent co-variables having been collected after the participant had been randomised to the trial and at the same time as the adherence data was being collected. As such temporality (cause preceding effect), one of the Bradford-Hill criteria (Hill, 1965) for determining causation, cannot be assumed for the intervention variables.

Data analysis

As an exploratory investigation no hypothesis was being tested, therefore exploratory data analysis techniques were employed to explore the relationships between the independent variables described above and adherence to practice (Tukey, 1977). All analysis was carried out using SPSS v25. The first step was to establish which of the demographic, clinical and intervention variables (i.e. independent variables) were associated with the dependent variable (total practice time) to determine which variables to include in the model. In order to achieve this, bivariate analyses were conducted using a correlation matrix for continuous variables, independent samples t-tests for binary categorical variables, and one-way ANOVA for categorical variables with two or more categories.

A multiple linear regression was carried out including all independent variables that were significantly associated ($p < 0.05$) with total practice time in the bivariate analyses. This conservative p-value cut-off (in the context of exploratory analysis; Mikey & Greenland, 1989) was selected based on a trial and error approach as it still allowed for a reasonable number of variables to be entered into the model. The model was adjusted for age and gender to ensure any findings were independent of these common confounders (Schneider et al, 2010). The original model violated the assumption for homogeneity of the variance (i.e. the variance within each population was not equal) so a sensitivity analysis was carried out using the square root of total practice time (the dependent variable), which significantly reduced the heteroscedasticity (meaning the points were more equally distributed across all values of the independent variables; Diah et al, 2012). In consultation with a senior statistician it was decided that the sensitivity analysis allowed the original model to be retained. Results of the original model and sensitivity analysis are reported. As an exploratory secondary analysis of trial data the analyses were not fully powered and this was taken into consideration when interpreting the results.

5.6 PART B: QUANTITATIVE RESULTS

Participants

97 participants were randomised to the intervention arm of the Big CACTUS study. Participants with no practice time data (n=9) or partial practice time data (3 or more months data not recorded; n=3) were excluded from this analysis. Reasons for missing data are provided in chapter four (page 119). Data from 85 participants were included in the analysis. See table 5.6 for participant's demographic characteristics.

Variables	N	Percentage
Gender		
Males	46	54.1
Females	39	45.9
Age groups		
≤55	20	23.5
56-65	19	22.4
66-75	24	28.2
≥76	22	25.9

Table 5.6. Demographic characteristics

Bivariate results

The results of the bivariate analyses are presented by variable group.

Demographic variables: As possible confounding variables it was decided that gender and age would be included in the base regression model irrespective of whether an association was established in the bivariate analyses. Male participants (M=50.70 hours, SD=50.97 hours) practised more than female participants (M=32.51 hours, SD=30.19 hours) and an independent samples t-test determined the difference was statistically significant ($t(74.789)=2.035, p=0.045$). Age was grouped into four categories with those aged 56-65 (M=60.43 hours, SD=42.71 hours) practising most and those aged 76 and over (M=30.16 hours, SD=40.86 hours) practising the least (see figure 5.10). However, a one-way ANOVA demonstrated that there were no statistically significant differences between age group means ($F(3,81)=1.956, p=0.127$).

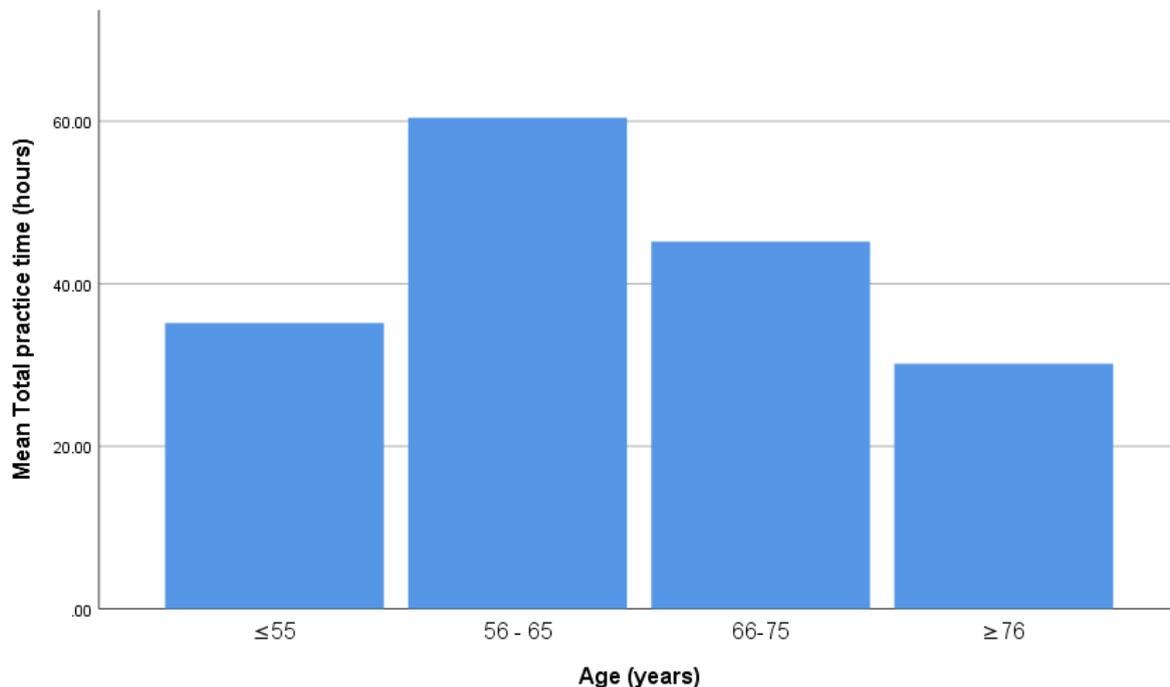


Figure 5.10. Bar chart showing the mean practice time by age group (years)

None of the other demographic variables were found to be significantly associated with total practice time. There was a trend for those with an informal carer (M=46.17 hours, SD=46.39 hours) to practise more than those without (M=29.08 hours, SD=28.21 hours), but an independent samples t-test established that this was not a statistically significant difference ($t(83)=-1.523$, $p=0.131$). There was also no significant difference in the amount of practice carried out by those who attended support groups (M=48.80 hours, SD=52.41 hours) compared to those who did not (M=36.34 hours, SD=32.46 hours) determined by an independent t-test ($t(65.87)=-1.306$, $p=0.196$). There was a trend towards those with internet access (M=47.28 hours, SD=35.06 hours) practising more than those without internet access (M=36.53 hours, SD=51.49 hours), however the results were not statistically significant as determined by an independent samples t-test ($t(83)=-1.14$, $p=0.258$). A one-way ANOVA established that there was also no statistically significant difference in practice time between the different sites ($F(20,64)=0.872$, $p=0.621$).

Clinical variables: There was a weak positive correlation (see figure 5.11) between total computer therapy practice time and number of years post-stroke ($r=0.23$, $n=85$, $p=0.04$). This was the only clinical variable found to have a statistically significant association and therefore the only clinical variable to go forward to the regression model.

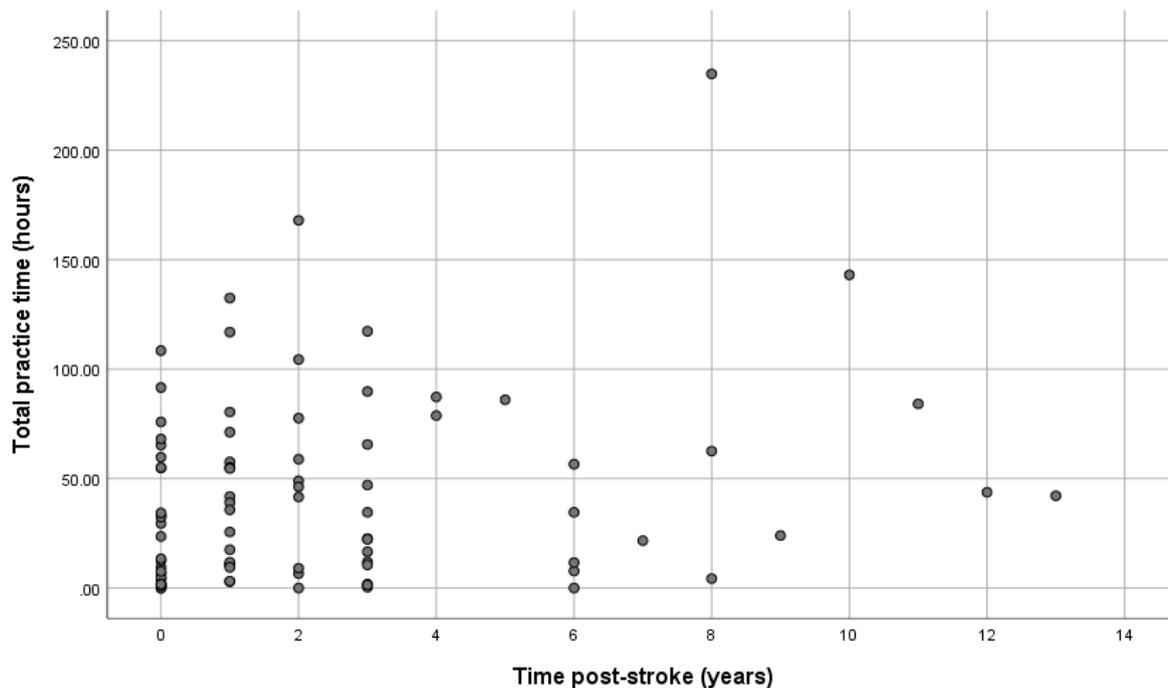


Figure 5.11. Scatterplot showing a weak positive relationship between time post-stroke and total practice time

A bivariate correlation matrix established that all other continuously measured clinical variables had weak negative non-statistically significant associations with total practice time: number of strokes ($r=-0.18$, $n=85$, $p=0.099$), severity of word-finding difficulty shown by CAT naming objects score ($r=-.052$, $n=85$, $p=0.634$), comprehension of spoken sentences ($r=-0.015$, $n=85$, $p=0.889$) and PWA rated perception of communication rated using the COAST ($r=-0.010$, $n=82$, $p=0.929$).

There was a trend towards those who had not received care in the last three months ($M=47.58$ hours, $SD=49.29$ hours) practising more than those who had received care ($M=36.46$ hours, $SD=35.44$ hours), however an independent samples t-test established this was not a statistically significant difference ($t(83)=1.181$, $p=0.241$). There was no statistically significant difference in total practice time between those with apraxia of speech ($M=40.67$ hours, $SD=37.90$ hours) and those without ($M=43.36$ hours, $SD=46.79$ hours) as shown by an independent samples t-test ($t(83)=0.275$, $p=0.784$). Figure 5.12 displays the mean practice times of participants with different types of aphasia; those with fluent aphasia practised most, however a one-way ANOVA found no statistically significant difference in practice time between the four groups ($F(3,81)=0.277$, $p=0.842$).

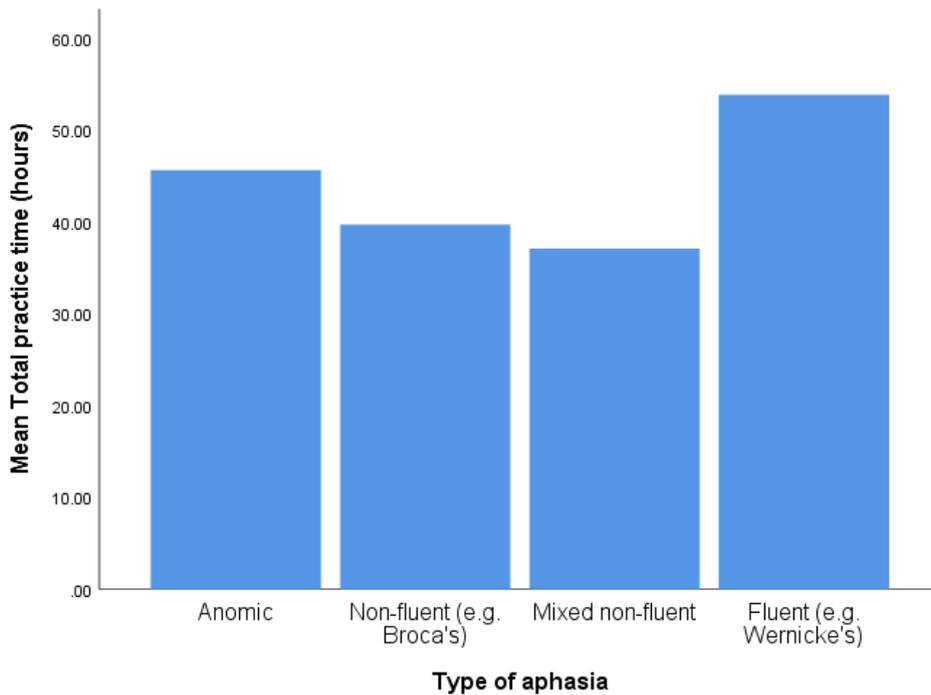


Figure 5.12. Bar chart showing the amount of practice (hours) carried out by participants with different types of aphasia

Intervention variables: Results from the intervention variables must be interpreted with greater caution than the demographic and clinical variables as they are not time dependent and causation is therefore less straightforward (e.g. it is possible that the amount of practice completed could have influenced the amount of support provided rather than the other way round).

Continuous variables were entered into a correlation matrix. Total practice time was found to be positively correlated with length of computer therapy access ($r=0.433$, $N=85$, $p=0.00$), therapist time spent supporting participants ($r=0.242$, $N=85$, $p=0.026$) and therapy assistant/volunteer session time spent with participants ($r=0.237$, $N=79$, $p=0.035$), see figure 5.13, 5.14 and 5.15 respectively. As these correlations were all statistically significant ($p<0.05$) they were included in the regression model.

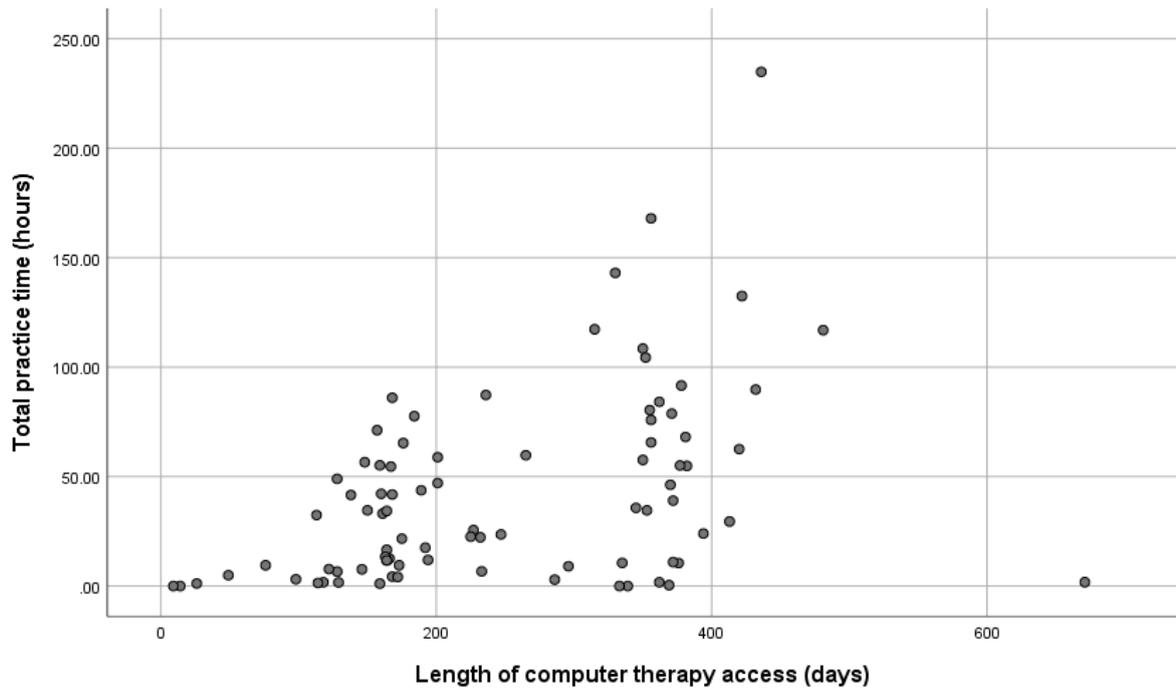


Figure 5.13. Scatterplot showing the moderate positive correlation between the length of computer therapy access and total practice time

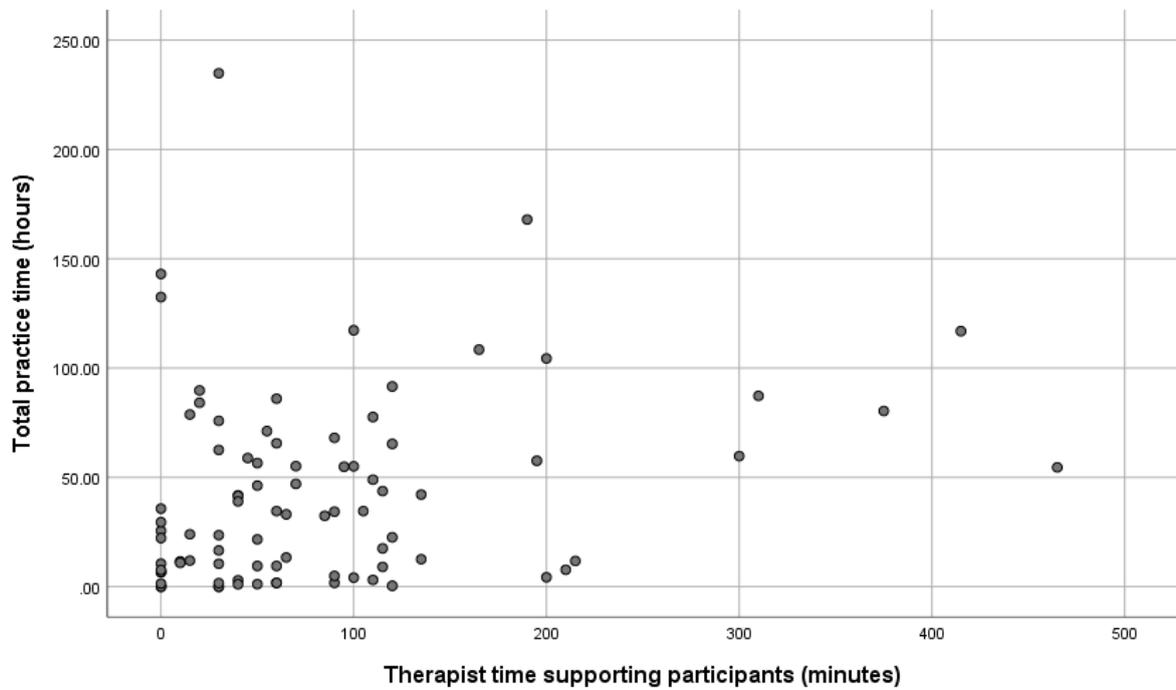


Figure 5.14. Scatterplot demonstrating the weak positive correlation between the amount of time the therapist spent supporting the participant and the total amount of practice carried out

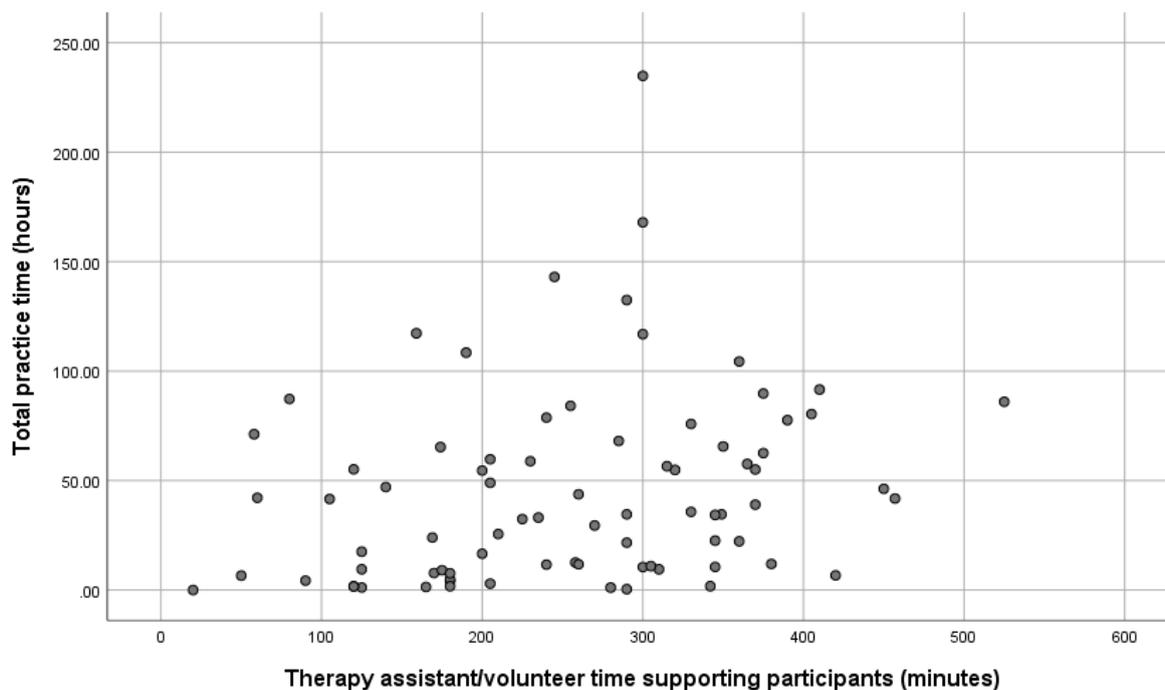


Figure 5.15. Scatterplot showing the weak positive correlation between therapy assistant/volunteer time supporting the participant and the amount of practice conducted

The amount of time the therapist spent with the therapy assistant or volunteer showed no linear relationship with the total amount of practice and was not statistically significant ($r=0.069$, $n=80$, $p=0.545$). There was a trend toward more practice being carried out by those participants who were practising on their own device ($M=50.44$ hours, $SD=34.76$ hours) rather than a device loaned to them ($M=38.79$ hours, $SD=46.58$ hours), however an independent samples t-test demonstrated that the difference was not statistically significant ($t(83)=1.141$, $p=0.257$).

Participants could practise on three types of device: the majority used a laptop ($N=70$, $M=41.09$ hours, $SD=39.70$ hours), some used a tablet ($N=12$, $M=52.83$ hours, $SD=65.05$ hours) and a small number used a desktop computer ($N=3$, $M=29.76$ hours, $SD=25.42$ hours). Whilst there was a trend for participants using the most portable device (tablet) to practise most and the least portable device (desktop computer) to practise least, the number of participants in the three groups was unequal and a one-way ANOVA showed that the difference between the groups was not statistically significant ($F(2,82)=0.498$, $P=0.609$).

Multivariate results

Multiple linear regression was carried out to investigate the relationship between practice time (hours) and time post-stroke (years), length of computer therapy access (days), therapist time supporting participant (minutes) and therapy assistant/volunteer time supporting participant (minutes). The regression model included data from 79 participants due to missing data. The analysis was controlled for age and gender. There was a statistically significant relationship between practice time and length of time post-stroke ($p=0.038$), computer therapy access ($p=0.003$) and therapist time supporting participant ($p=0.043$). For each additional year post-stroke there was a 3.018 hour (i.e. 3 hours 1 minute) increase in practice time. For each additional day of computer therapy access, there was a 0.124 hour (i.e. 7 minute) increase in practice time. Furthermore, for each additional minute the therapist spent providing support (including technical support and monitoring/adapting exercises) to the participant the total practice time increased by 0.098 hours (i.e. 6 minutes).

The relationship was not statistically significant between practice time and gender ($p=0.110$), age ($p=0.556$) or therapy assistant/volunteer time supporting participant ($p=0.233$). Despite being non-significant age and gender were retained in the model to adjust for these factors. Therapy assistant/volunteer time supporting the participant would have been removed from the model due to non-significance, however it was retained because it was identified to be significant in the sensitivity analysis (discussed below). See table 5.7 for coefficients and P values for all variables in both the original and square root model.

The R^2 value for the original model was 0.29 so 29% of the variation in practice time can be explained by the model containing age, gender, time post-stroke, length of computer therapy access, therapist time supporting the participant and therapy assistant/volunteer time supporting the participant.

Variable	Original model			Square root model		
	Coefficient	P value	Confidence interval	Coefficient	P value	Confidence interval
Constant	-1.945	0.929	-45.013 – 41.124	2.081	0.204	-1.156 – 5.318
Time post-stroke (years)	3.018*	0.038	0.170 – 5.866	0.241*	0.028	0.027 – 0.455
Length of computer therapy access (days)	0.124*	0.003	0.043 – 0.204	0.007*	0.029	0.001 – 0.013
Therapy assistant/volunteer time supporting participant (minutes)	0.054	0.233	-0.036 – 0.144	0.007*	0.041	0 – 0.014
Therapist time supporting participant (minutes)	0.098*	0.043	0.003 – 0.193	0.009*	0.020	0.001 – 0.016
Sex	-14.453	0.110	-32.233 – 3.327	-0.635	0.347	-1.971 – 0.701
Age (years)	2.400	0.556	-5.686 – 10.485	-0.071	0.818	-0.678 – 0.537

Table 5.7. Regression coefficients and p values for the original and square root multiple linear regression models (significant at 5% level)*

A histogram demonstrated that the residuals were approximately normally distributed, however the scatterplot of standardized predicted values versus standardised residuals indicated that the data did not meet the assumption of homoscedasticity. The sensitivity analysis allowed for the assumption of homoscedasticity to be met (see figure 5.16), thus confirming the findings of the original model. One notable difference between the two models was that therapy assistant/volunteer time supporting participants, which was not significantly associated with practice time in the original regression model, was found to be statistically significant in the square root model. This will be taken into consideration in the interpretation of results in the discussion.

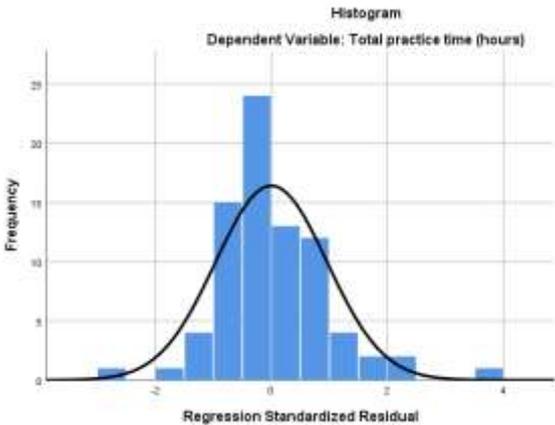
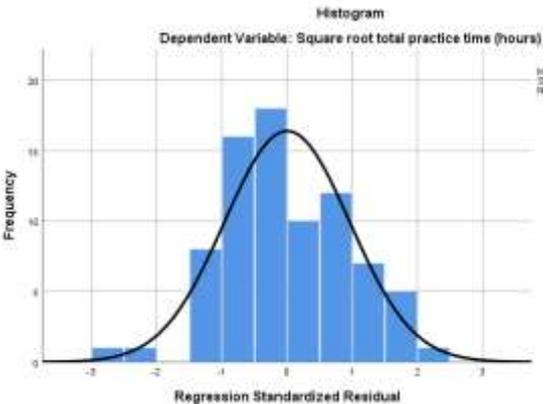
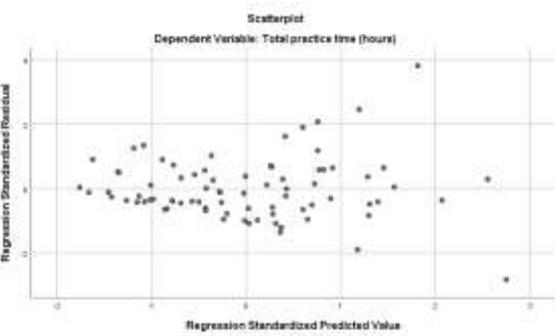
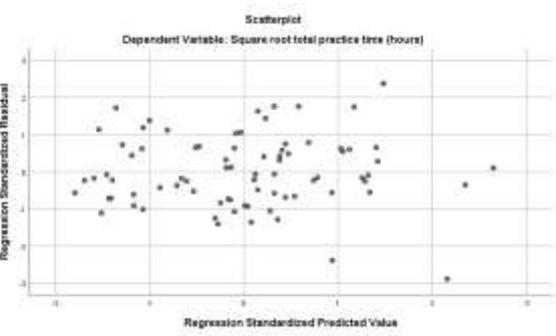
Original model	Square root model
<p>Normality of residuals: residuals are approximately normally distributed</p> 	<p>Normality of residuals: normal distribution improved through square root transformation</p> 
<p>Homoscedasticity: cone shaped pattern shows that the variance of the residuals increased as the predicted values increased</p> 	<p>Homoscedasticity: the cone shaped pattern is significantly reduced indicating that the assumption for homoscedasticity has been met through square root transformation</p> 

Figure 5.16. Histograms and scatterplots exploring statistical assumptions for the original and square root regression model

Quantitative summary/discussion

This secondary analysis sought to explore the patient, clinical and intervention related characteristics associated with adherence to aphasia computer therapy practice in the long-term post stroke. At a clinical level, greater length of time post-stroke was associated with better adherence to aphasia computer therapy practice. At an intervention level, length of computer therapy access and more therapist time supporting the participant (which included technical support and the therapist monitoring the participant's progress directly or indirectly and making adaptations to the therapy exercises) was associated with greater adherence to aphasia computer therapy practice. Furthermore, an additional intervention variable, therapy assistant/volunteer time supporting the participant, was associated with greater adherence in the square root regression model, but not in the original model. At a patient level, none of the demographic characteristics had a statistically significant association with adherence, although male participants did practise more than female participants and this was found to be statistically significant in the bivariate analysis.

One of the reasons for attempting to deliver aphasia therapy in a self-managed computerised form is to enable the provision of speech and language therapy in the longer term post-stroke as evidence has demonstrated the effectiveness of such provision (>six months; Allen et al, 2012). Despite evidence of effectiveness, it has been established that PWA in the UK receive less face-to-face SLT the more time that has passed since their stroke (Palmer et al, 2018). The finding that length of time post-stroke was associated with better adherence suggests that the intervention is possibly better suited to those in the longer-term post stroke. This is consistent with Cochrane review findings that participants have greater tolerance (indicated by lower drop-out rates) for high intensity therapy when the intervention is delivered further post-stroke (Brady et al, 2016). In the initial aftermath of a stroke there is a lot of change both mentally, in terms of psychological adjustment, and physically, in terms of receiving other care and rehabilitation interventions. The increased tolerance/adherence could be due to the PWA having more time to focus on therapy or due to a greater understanding of their condition. This finding warrants further investigation.

Engaging with aphasia computer therapy, or any self-managed rehabilitation intervention, requires behaviour change. The COM-B system of behaviour change emphasises the importance of opportunity (Michie et al, 2011). In order to have the opportunity to engage with the therapy it must be accessible to the participant. It follows, therefore, that providing a longer period of access to the therapy was associated with more practice being carried out as greater opportunity was provided.

The amount of time spent by the therapist supporting, monitoring and adapting the software was found to be predictive of adherence to aphasia computer therapy. Similar findings were identified in a study investigating adherence to home-based exercise programs for neck and low back pain in which patients who received frequent supervision of their exercises had higher levels of adherence (Medina-Mirapeix et al, 2009). Whilst only identified in the square root model and thus to be interpreted with caution, the finding that assistant/volunteer support was associated with more practice time echoed findings from the CACTUS pilot study, in which most of the participants (3/4) who did not carry out the recommended amount of practice had not received contact from volunteers (Palmer et al, 2012). These findings are indicative of the impact that on-going support and monitoring can have on patient adherence to aphasia computer therapy.

Research from the fields of medicine (DiMatteo, 2004) and home based physical therapy (Essery et al, 2017) have found social support (from practical support to being married) to be predictive of adherence. Therefore, one might have anticipated that the presence of an informal carer (spouse, family or friend) would have been associated with adherence in the Big CACTUS study, however this was not found to be the case. The measure of social support was whether someone had self-identified as a carer for the purpose of completing the carer outcome measures in the Big CACTUS trial. A more sensitive measure of social support might have yielded different results.

Gender did not have a significant impact on adherence in the multivariate model, but it did demonstrate a significant difference in univariate analysis with men practising more than women. This finding is contrary to adherence to other interventions. A review of reviews on medication adherence found female gender had a positive impact on adherence and male gender a negative impact (Kardas et al, 2013). However, as a computerised intervention, adherence might be affected by attitudes toward technology use. A recent meta-analysis found males hold a more favourable attitude toward technology than females (Cai et al, 2017).

5.7 PART C: TRIANGULATION METHOD

Design

The third part of this chapter describes the triangulation of data collected in part A and B. In aiming to explore what factors are associated with adherence to aphasia computer therapy practice? Qualitative interviews provided the opportunity to comprehensively answer the question from the perspective of PWA and their carers, but the wealth of quantitative Big CACTUS trial data meant it was also possible to explore the question quantitatively using secondary data analysis. It is recommended that each dataset should be analysed in isolation prior to integration at the interpretation stage (O’Cathain et al, 2010). Similarly to Heslehurst and colleagues (2015), the approach adopted combined ‘following a thread’ and applying a ‘convergence coding matrix’. ‘Following a thread’ refers to selecting a theme or finding from one dataset and following it across to the other dataset (Moran-Ellis et al, 2006). The production of a convergence coding matrix is one of the key elements of Farmer et al’s (2006) triangulation protocol. This involves displaying the findings from each study together and consideration of the extent to which the findings converge.

Method and Analysis

The following a thread method involved identifying a thread from the qualitative interviews (i.e. factor associated with adherence) and then searching the quantitative data for related data (threads). The qualitative data continued to be grouped according to the COM-B system (Michie et al, 2011), thus enabling the quantitative data to be considered in light of this behaviour change model. The convergence coding matrix was used to integrate the threads and convergence was coded using the following criteria used by Heslehurst et al (2015; adapted from Farmer et al, 2006):

- “1. Convergence: where findings directly agree
2. Complementary: findings offer complementary information on the same issue
3. Dissonance: findings appear to contradict one another
4. Silence: themes arising from one component study but not others”

From part B, only variables found to be associated with adherence to aphasia computer therapy practice in the multivariate analysis have been included in the triangulation.

5.8 PART C: TRIANGULATION RESULTS

The results of the convergence assessment are shown in table 5.8 and discussed below.

Elements from the COM-B system used to frame integration	Factors associated with adherence identified through interview data	Factors associated with adherence identified through secondary data analysis of Big CACTUS trial data	Convergence assessment
Physical capability	↓ Ability to use computer therapy software	N/A	Silence
	↑ Assistants/ volunteers helped PWA to develop the skills required to use the computer therapy	↑Assistant/ volunteer spending more time supporting the participant	Complementary
Psychological capability	↑ Knowledge of recommended practice time	N/A	Silence
	↑Understanding/knowledge of own condition	N/A	Silence
	Cognitive impairment and fatigue (↓forgetting; ↓concentration problems; ↓fatigue; ↑strategies to overcome e.g. practice certain times of day)	↑Longer length of time post stroke	Complementary
Physical opportunity	Features of the software that facilitated more practice (↑ personalisation of vocabulary; ↑therapy in home environment; ↑ independence HA only)	N/A	Silence
	Barriers to practice (↓periods of illness; ↓other commitments; ↓engaging in alternative therapeutic activities)	↑Longer length of time post stroke	Complementary
	Computer therapy software problems (↓issues with voice recognition; ↓stability of the software; ↑stability of the software was improved via software updates) ↓Computer hardware problems	↑Computer therapy available for longer	Complementary
	Availability of support (↑more input from supporters; ↓supporter visits not helpful LA only; ↑informal carers of participants who could not use computer therapy independently)	↑Therapist spending more time supporting the participant ↑Assistant/ volunteer spending more time supporting the participant	Convergence and dissonance
Social opportunity	↑ External support (importance of input from SLT or volunteer/ assistant) ↑ Social pressure (caused by impending visit from supporter)	↑Therapist spending more time supporting the participant ↑Assistant/ volunteer spending more time supporting the participant	Complementary

Reflective motivation	Beliefs about capability (↓capability concerns often based on lack of prior computer experience; ↑high self-efficacy HA only)	N/A	Silence
	Beliefs about consequences (↑expectation of anticipated outcome influenced by supporters; ↓pessimism)	N/A	Silence
	Goals (↑distal goal associated with regular practice; ↑proximal goal associated with longer practice session; ↓mismatch between personal goal and intended outcome of computer therapy)	N/A	Silence
	Stability of intentions (↓ LA described decline over time)	N/A	Silence
	Differing intention between PWA and carer (↓carer more motivated than PWA; ↑ PWA obsessed carer encouraging less practice)	N/A	Silence
Automatic motivation	Emotion (↓low mood or negative attitude on given day)	N/A	Silence
	Personality (↑determined/perfectionist)	N/A	Silence
	Habit (↑routine pattern of practice)	N/A	Silence
	↑Obsession (impulse to practice detrimental to other activities)	N/A	Silence
	Reinforcement (↑feedback about practice time; ↓feedback about performance)	N/A	Silence

Table 5.8. Convergence coding matrix (↓ = factor associated with less practice; ↑ = factor associated with more practice; ↕ = factor associated both with more and less practice)

Only four factors associated with adherence were identified from the quantitative results compared to 19 from the qualitative results. The qualitative data was anticipated to be more comprehensive and was therefore used as the basis of the ‘following a thread’ method.

Physical capability to carry out the computer therapy was perceived to influence the amount of practice people were able to carry out. There was recognition of the vital role assistants/volunteers played in participants developing their skills to be able to use the computer software. This provides a potential explanation for why the assistants/volunteers spending more time supporting the participant was found to be associated with greater adherence in the square root analysis. The psychological capability of participants to adhere to regular computer therapy practice was perceived to have been impeded by cognitive impairment and fatigue, both of which can improve over time, which could potentially provide a possible explanation for the quantitative finding that people were more adherent the more time had passed since their stroke. All findings about PWA’s capability to use the computer therapy were complementary.

In itself the passing of time is unlikely to have resulted in greater adherence. More likely it is a proxy for recovery, as described above, or lifestyle changes that have taken place over time. Some of the barriers to practice which reduced the participants' physical opportunity to practise included having other commitments or engaging in alternative therapeutic activities. It is possible that participants might have less other commitments or less opportunity to engage in alternative therapeutic activities, the more time that has elapsed since their stroke, thus reducing some of the barriers identified in the qualitative interviews. Another factor perceived to reduce participant's physical opportunity to practise was problems with the computer therapy software and computer hardware, both of which resulted in the computer therapy being available to the participant for less time. This provides a possible explanation for why the length of time the computer therapy was available to participants was significantly associated with adherence in the quantitative findings.

The broad consensus from the qualitative data was that high adhering participants perceived greater availability of support (from both therapists and assistants/volunteers) enabled more practice and some low adherers who perceived they did not have enough support felt they would have been able to practise more with more support. This finding demonstrates convergence with the quantitative findings that the therapist and assistant/volunteer spending more time supporting the participant was significantly associated with greater adherence. However, within the same qualitative factor it was also noted that a small number of low adhering participants did not perceive the supporter visits to be helpful. This finding contradicts the general consensus from the qualitative data and the quantitative finding that more support was associated with more practice. It might indicate that there is a small group for whom no matter how much additional support is provided it will not encourage more practice, or that the relationship between some participants and their assistants/volunteers were not as good as others, which is the information the Working Alliance Inventory might have captured had the data been more complete. The same quantitative finding that more support from therapists and assistants/volunteers facilitated more practice was also complementary in terms of the qualitative finding that external support was perceived to be more beneficial due to the social pressure created by that support not being provided by someone well known to them. This demonstrates the importance of providing 'outside' support rather than relying on carer support.

None of the data available for use in the quantitative analysis corresponded with any of the factors relating to motivation meaning there was silence across all factors associated with motivation.

Triangulation summary/discussion

The triangulation of qualitative and quantitative data provides a summary of those findings for which some agreement or dissonance was apparent. The large amount of silence reflects the limited scope of the quantitative findings, rather than indicating a deeper meaning. The qualitative findings were more detailed and comprehensive providing possible explanations for the quantitative findings relating to PWA's capability to use the computer therapy and having the opportunity to practise. Convergence was found for support contributed by therapists and assistants/volunteers, which was identified to be associated with greater adherence in the qualitative and quantitative data. The same factor also demonstrated dissonance as there were also a small number of low adhering participants who did not find support to be beneficial, but that view was only expressed by those who barely engaged with the therapy. There was silence across the whole theme of motivation as none of the quantitative factors found to be associated with adherence were related to the findings in that theme. The quantitative data was not sufficiently detailed to allow the production of meta-themes as has been suggested by qualitative triangulation protocols (Farmer et al, 2006) frequently utilised in mixed methods research (O'Cathain et al, 2010).

5.9 OVERARCHING DISCUSSION

All three sets of findings have been summarised in the discussions at the end of each section (see pages 189, 204 and 210). This overarching discussion focuses on the implications for clinical practice and intervention development, the strengths and limitations of the study, as well as future research.

Implications for clinical practice and intervention development

Clinicians delivering computer therapy should consider the capability of participants to use the computer therapy, including factors such as, cognitive impairment, understanding of their condition, knowledge of the intervention and the role supporters can play in skill development. Furthermore, PWA might have more capability and opportunity to use the computer therapy once more time has passed since their stroke. Clinicians play a vital role in providing the opportunity to practise, which was as much about the need for support from SLTs and volunteers/assistants as it was about ensuring the computer therapy was available for a long period. One of the key roles of the supporters was to provide technical support, which was required to overcome the technological issues with the computer therapy

highlighted in this study. Clinicians should also consider how the motivation of the PWA might influence their decision to practise, with potentially modifiable motivational factors including creating shared goals and beliefs about the computer therapy, ensuring feedback on performance from the computer therapy is accurate (or hiding that option) and helping the PWA to develop a practice routine.

The COM-B system, which has informed this chapter, forms the hub of the Behaviour Change Wheel (BCW: Michie et al, 2011). The outer two layers of the BCW identify intervention functions and policy categories that can be incorporated or adapted to enable an intervention to effect behaviour change (see figure 5.17). Each of the intervention functions from the BCW that could apply to the StepByStep approach, including incentivisation, education, training, environmental restructuring and enablement, have been considered to identify how they could be adapted to increase the amount of practice carried out by PWA.

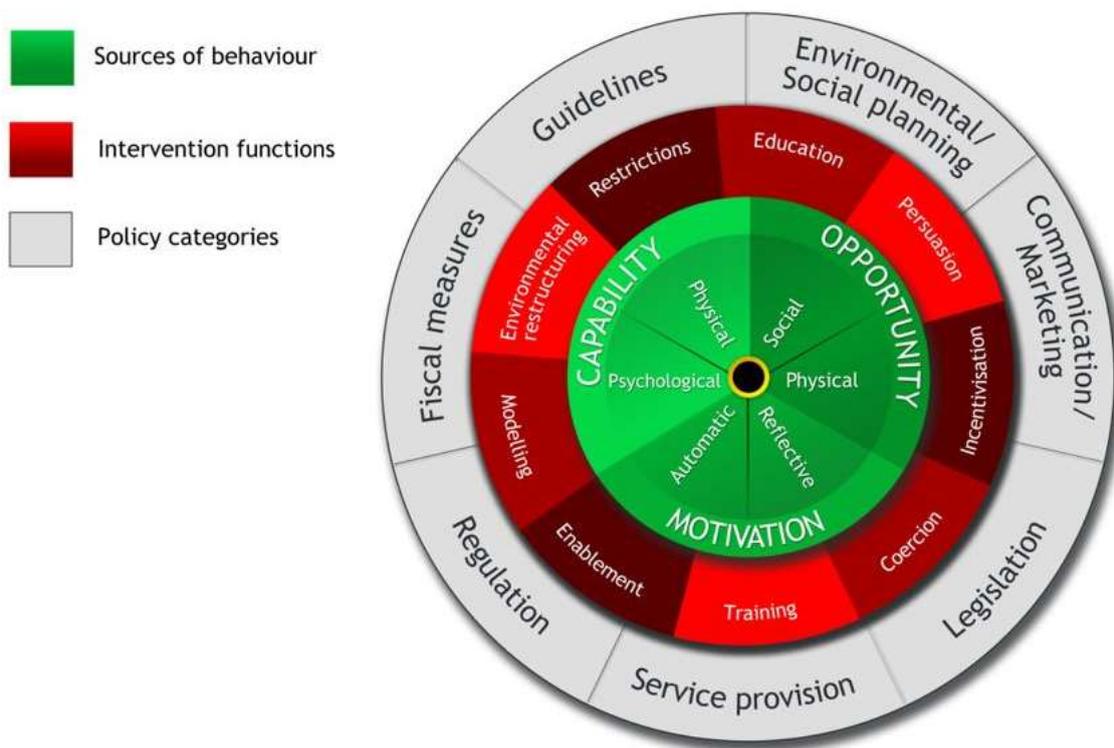


Figure 5.17. Behaviour Change Wheel (Michie et al, 2011; licenced under CC BY 4.0; reproduced with no changes)

Feedback provided by the StepByStep software provided an incentive to practise. Feedback on the amount of practice motivated more practice, however feedback on performance was only perceived to be motivating when the feedback was accurate. When the voice recognition failed to recognise correct answers it resulted in frustration and reduced motivation to practise. Improvement of the voice recognition by the software developers would increase the reliability of this incentive thus increasing automatic motivation. The only finding from the triangulation for which qualitative and quantitative data converged was the finding that more support was associated with more practice (except for a very small number of low adhering participants in the qualitative interviews). Therapists and assistants/volunteers were responsible for training and educating participants about the intervention. Having more time to provide training and education would have the potential to target multiple elements of the COM-B behaviour change system through developing the skills to use the computer therapy (i.e. physical capability), increasing knowledge of recommended practice time (i.e. psychological capability) and knowledge about the potential consequences of the intervention (i.e. reflective motivation). Therefore, a clinical recommendation would be to ensure sufficient therapist and assistant/volunteer time is available and intervention development work could include amending training materials to reflect the importance of helping PWA to understand the intervention, the potential benefits and develop the necessary skills to use the computer therapy. Environmental restructuring (e.g. extended loan periods/ installing software on participants own device) and enablement (prompt input from therapists and assistants/volunteers and software developers to reduce the impact of software and hardware problems) are both functions that could be targeted to increase the physical opportunity to practise. Furthermore targeting the therapy at those participants who had their stroke a longer time ago might enable more therapy by reducing potential barriers highlighted by some participants in the qualitative interviews such as engaging in other therapies or having too many other commitments.

Strengths and limitations

This is the first in depth exploration of adherence to self-managed aphasia computer therapy. The qualitative interviews facilitated the inclusion of people with communication impairment, who would often be excluded from interviews in other health care research. Additionally, inclusion of the views of participants with all severities of aphasia was achieved by interviewing the carers of people with more severe aphasia. Considerably more male PWA (83%) were recruited to the qualitative interviews. The Big CACTUS study as a whole has a slight gender bias toward male participants (60%; Palmer et al, 2019); contrary to a

recent review which found that aphasia rates are higher in women (Wallentin, 2018). The increased gender difference in this sample compared to the wider Big CACTUS sample might have been due to self-selection of participants agreeing to participate in the study, but it might also have been influenced by the eligibility criteria participants had to meet relating to study site location and language comprehension. In the interviews, participants were asked about their expectations of aphasia computer therapy prior to receiving the intervention. Whilst all participants responded to this question it is not possible to know if the expectations they have described feeling prior to starting to use the computer therapy have been influenced by their subsequent experience of using or not using the computer therapy due to the limitations of human memory.

The utilisation of RCT data in the secondary data analysis section afforded some advantages, a particular strength being a relatively large sample size and rigorous data collection processes. However, the limitation of using data collected for the purposes of the trial meant that important variables relating to adherence, identified in the qualitative interviews, were not measured. This may explain the regression model only accounting for 29% of the variation in practice time. It is possible the model would have benefitted from the inclusion of variables such as self-efficacy (Essery et al, 2017), intrinsic motivation (Jurkiewicz, 2011), executive function (found to be predictive of rehabilitation participation; Skidmore et al, 2010), technology proficiency and a more sensitive measure of social support. However, finding valid quantitative measures of these variables that are accessible to PWA would be a challenge. Furthermore, whilst the sample was not small, it was powered to find a change in word-finding ability for the Big CACTUS trial, not to predict factors associated with adherence to the intervention.

Three of the factors found to be associated with adherence to aphasia computer therapy were intervention variables: length of access to computer therapy, therapist time supporting the participant and volunteer/assistant time supporting the participant. Intervention variable data was collected in parallel with practice time data (rather than prior to randomisation like the patient and clinical variables) meaning that the assumption of causation is less clear. It is possible that the intervention variables could have been impacted upon by low adherence (e.g. participant not using the therapy so asks for the computer to be removed). There was a high variability (indicated by high standard deviations throughout), a positive skew and some outliers (particularly high adhering participants) in the dependent variable (practice time). Regression can be particularly sensitive to outliers, but as there was no evidence that the data were inaccurate outliers were not removed. The square root sensitivity analysis reduced the variability, the skew and the impact of outliers, thus improving the normality of the data (Osborne, 2005). The process of bivariate testing used to select variables for

inclusion in the regression model is criticised by some statisticians for increasing the likelihood of an “overfitted” model with an increased risk of a type I error (Babyak, 2004). However, due to the lack of prior research around predictors of adherence to speech and language therapy interventions for aphasia there was no prior evidence or theory upon which the decision of which factors to include could be made. Conclusions must be interpreted in light of the fact that this was exploratory research.

Future research

As described above, the limited quantitative findings (four factors found to be associated with adherence) did not influence interpretation of the findings in such a way that it was possible to create meta-themes across the two data sources. However, process data related to adherence was also described in chapter four. A further triangulation could be carried out to assimilate the three data sources, however this was beyond the scope of this chapter/PhD. Additionally, it would be interesting to explore how some of the factors relating to reflective and automatic motivation that arose from the qualitative data could be measured quantitatively through the identification or development of measurement tools to enable this to be explored in more depth in future research.

Participants in the Big CACTUS study could engage in as much computer therapy practice as they chose. As a pragmatic, effectiveness trial, the only strategies used to increase adherence were those already built into the intervention (e.g. training and encouragement from supporters). It has been noted in the Cochrane review of speech and language therapy for aphasia following a stroke that studies of high dose and high intensity therapies have higher dropout indicating that they are less acceptable to some participants (Brady et al, 2016). The findings of this research could feed into the iterative process of intervention development and evaluation. For example, the computer therapy could be offered for longer, more therapist and assistant/volunteer time could be provided and the training offered to therapists and assistants/volunteers could be adapted to include factors identified within this research in order to increase adherence. This could include the importance of helping the PWA consider how computer therapy practice could become a part of their daily routine and ensuring it is the PWA rather than the carer who is motivated to get involved.

Conclusion

The factors identified as being associated with adherence to aphasia computer therapy practice were integrated using the COM-B system (Michie et al, 2011). Clinicians and intervention developers should consider factors relating to capability (cognitive impairment, fatigue, level of understanding of condition, knowledge of the intervention), opportunity (more time having elapsed post-stroke, having access to the computer therapy for longer, receiving more support from therapists and volunteers/assistants, and software and hardware problems) and motivation (beliefs about their own capability, reinforcement via feedback from software, emotion, personality and habit) to practice identified in the study when delivering and developing the intervention in order to facilitate increased adherence. These findings are an important first step toward understanding potentially modifiable factors that contribute to adherence to self-managed computer based rehabilitation interventions in the longer-term post-stroke.

Chapter Six: How Does Intervention Delivery Affect Outcome? A Component Analysis

This chapter aims to identify the 'essential' components of the StepByStep approach to aphasia computer therapy. The term 'essential' component has been used throughout this chapter to follow the terminology used in the Conceptual Framework for Implementation Fidelity (CFIF; Carroll et al, 2007), however it is worth noting that these are components for which the quantity or quality of delivery of the component are tentatively associated with improved word-finding based on exploratory data analysis.

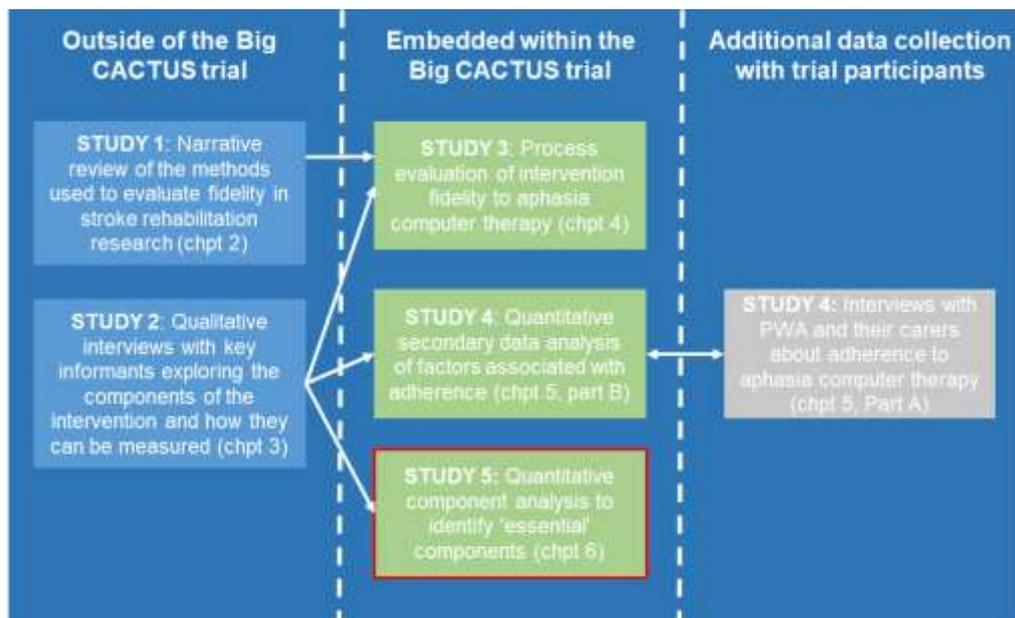


Figure 6.1. PhD structure with red border indicating current chapter

6.1 INTRODUCTION

Treatment differentiation, which originally referred to there being sufficient difference between an intervention and control condition, has long been conceptualised as an element of fidelity (Monscher & Prince, 1991). Implementation scientists rebranded the same concept *program differentiation*, which they defined as "identifying unique features of different components or programs" to determine "which elements of . . . programmes are essential" and without which the intended effect would not be produced (Dusenbury et al, 2003). The Conceptual Framework for Implementation Fidelity (CFIF) proposed by Carroll et al (2007), which has underpinned the evaluation of fidelity to the StepByStep approach throughout this thesis, further re-defined this as "identification of an intervention's essential components". Carroll et al (2007) suggest this process of identifying essential components, whilst related to fidelity, is actually a distinct activity. The CFIF, shown in figure 6.2, positions component analysis beyond fidelity evaluation and prior to further evaluation of the intervention.

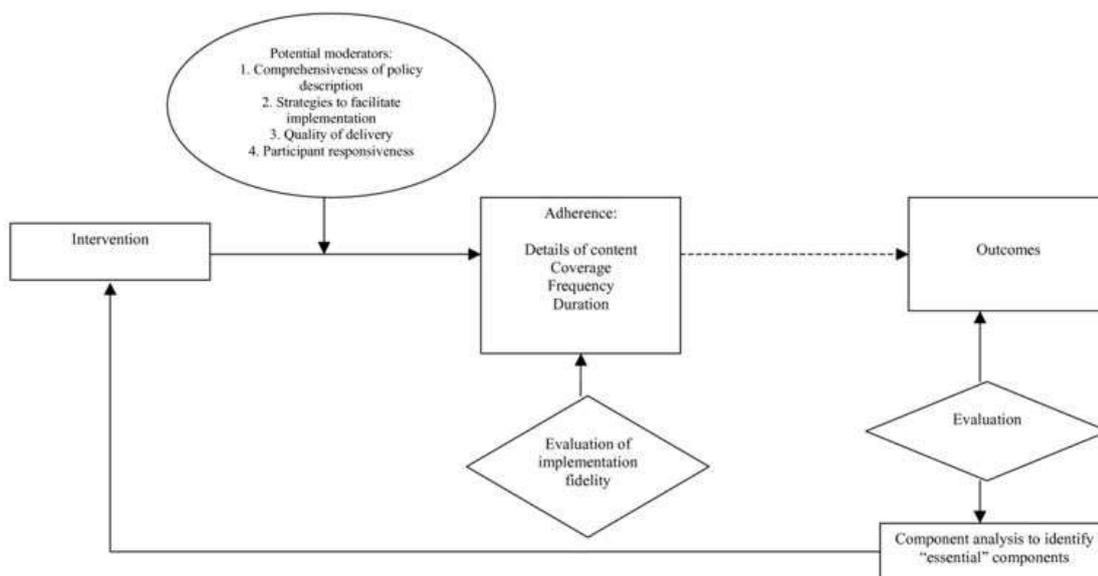


Figure 6.2. Conceptual Framework for Implementation Fidelity (Carroll et al, 2007; licenced under CC BY 4.0; reproduced with no changes)

A 'component analysis' can contribute to the process of iterative intervention development, as well as having significant implications for intervention fidelity. For example, if we do not know which are the 'essential components' of an intervention and clinicians only implement certain components, but not the 'essential' components, then it would be unlikely the desired outcome would be achieved. This process has the potential to refine the StepByStep intervention and/or enable therapists to focus on implementing the most important aspects of the intervention, whilst still achieving the desired outcome in an environment where time and resources are scarce, thus resulting in possible time and cost-efficiency savings.

Component analysis would ideally incorporate data from multiple studies using meta-analysis or meta-synthesis approaches to determine the essential components (Sutcliffe et al, 2015). However, in the absence of multiple trials of similar interventions, as is the case for the StepByStep intervention, it is still possible to explore the relationship between the extent to which the hypothesised 'essential components' are delivered and the extent to which the desired outcome is achieved within a single study, provided the intervention had the potential to be delivered differently. For example, efficacy studies which tightly control intervention delivery or studies with small numbers of participants would not have sufficient variation to allow for differences between intervention delivery and outcome to be explored. However, as Big CACTUS was a pragmatic trial of intervention effectiveness conducted across 21 SLT departments differences in delivery will be inherent in the data collected.

The aim of the study described in this chapter, was to establish whether any components of the StepByStep approach to aphasia therapy are 'essential' to produce the desired outcome. Key informants opinions were sought in study two (chapter three) to identify the ten most important aspects of the intervention to measure to determine whether the perceived key components of the intervention were being delivered and received as intended. These items formed the basis of the component analysis described in this chapter. The desired outcome of the StepByStep intervention, identified by the Big CACTUS trial team, was to improve participant's word-finding ability (measured using a naming test of personal vocabulary) and functional communication (measured on conversation rated using the activity scale of the Therapy Outcome Measures [TOMs; Enderby et al, 2013]). The trial therefore had co-primary outcome measures because, whilst generalisation to functional communication was the ultimate goal of the therapy, improved word-finding was still a desired outcome in its own right as the first step to achieving the ultimate goal. The Big CACTUS trial found a significant improvement in word-finding ability in the computer therapy group compared to usual care and attention control, but no significant difference between groups on the TOMs, indicating the improvement had not generalised into functional conversation (Palmer et al, in press). However, the authors of the Big CACTUS HTA report acknowledge uncertainty about how best to measure changes in conversation (Palmer et al, in press) and questions have been raised about the sensitivity of the TOMs to detect small changes (John et al, 2011). Since no difference was shown in functional communication between groups in the trial and the sensitivity of the TOMs was a source of potential concern, only the word-finding outcome was included in the component analysis for the purpose of this thesis. It is worth noting that there was an additional secondary measure of functional communication (count of personally relevant words used in conversation), but as it was a secondary outcome of the trial it has not been included in this initial analysis.

6.2 METHOD

Design

Secondary analysis of Big CACTUS trial data investigated the relationship between change in word-finding ability over the six month intervention period and scores relating to the delivery or receipt of key components of the aphasia computer therapy intervention. The measures of key components were those identified as being important to monitor for a fidelity evaluation by key informants in qualitative interviews in chapter three.

Participants

Data from all Big CACTUS trial participants randomised to the intervention arm, with baseline and six month outcome measures, were eligible for inclusion in this analysis. Big CACTUS study eligibility criteria are detailed in chapter one (page 38).

Procedure and ethical approval

Staff from the Clinical Trials Research Unit helped the author to extract data from the Big CACTUS trial database. The author cleaned, collated and prepared the data for analysis in SPSS. Ethical approval for this sub-analysis of data from the Big CACTUS trial was granted by Leeds West Research Ethics Committee (REC) (see appendix F) and the Scottish A REC (see appendix G) through an amendment to the protocol (version 4.0, 17 July 2015) for the Big CACTUS trial (ISRCTN: 68798818).

Measures

As described in the introduction, the desired outcome (i.e. dependent variable) was change in word-finding ability, between baseline and six months, measured using a naming test of personally relevant vocabulary. Participants were asked to name 100 words with a maximum score of two points each (2=correct response; 1=correct response following repetition of the question, self-correction or delay of five seconds, 0=incorrect). The pictures were presented in the assessment section of the StepByStep software.

The measures of delivery and receipt of key components of the intervention (i.e. independent variables) explored in this analysis were selected in key informant interviews in chapter three and collection of the data has previously been described in detail in the process evaluation in chapter four. The components and methods of measurement are summarised in table 6.1 with additional information described below for measures requiring more detail (marked with *).

Intervention component	Aspects of intervention delivery/receipt selected for measurement by key informants	What was actually measured and how
StepByStep software	Availability of the software (during the time the patient should have the software)	The number of days the software was available to the participant in the six months post randomisation was calculated based on documentation completed by therapists detailing the date provided, removed and any periods of inaccessibility
	Ease of use of the software	Question about ease of use of software using a visual analogue scale to record response from 1-10 completed by PWA
Therapy set-up: tailoring and personalising	How skilled the person assessing the patient and setting up the software is	Therapist skill/knowledge of intervention set-up and assessment process determined by their mean score (maximum 15 points) on the lead therapist quiz across three time points (5, 10 and 15 months)
	What sequence of steps are selected and why (e.g. justification for tailoring)	Therapy planning form assessed for completion on a 3-point scale*
	How much the words/photos have been personalised	Question about PWA perception of personalisation using a visual analogue scale to record response on a 5-point scale from 'All' to 'None' completed by PWA
Regular independent practice	Patient motivation	Question about level of motivation using a visual analogue scale to record response from 1-10 completed by PWA
	How much people practise	Total amount of practice completed within six months of randomisation recorded by the electronic StepByStep key file
	What people practise	The amount of time spent on the different types of therapy exercises (picture recognition, confrontation naming, using writing to cue naming, naming in a grid and naming in functional sentences) recorded by the electronic StepByStep key file
Supporting and monitoring practice	How the steps are adjusted or adapted in response to the PWA's performance	Whether or not adaptations were made following initial tailoring of the StepByStep software as recorded by therapists on the final page of the Therapy Planning Form*
	How good the relationship is between the supporter (volunteer or assistant) and the PWA	Composite score on 'Working Alliance Inventory – Short Revised Therapist' (WAI-SRT) completed by volunteer or assistant four months into the intervention period

Table 6.1. Aspects of intervention delivery and receipt identified by key informants in study two grouped by intervention component and the associated method of measurement (more detail provided below)*

Key informants recommended we measured how the therapy exercises were adjusted or adapted in response to the PWA's performance. This was described in detail using content analysis of therapists' free text comments on the therapy planning form within the process evaluation (chapter four). However, 'how' is a difficult concept to quantify numerically, so for the purpose of this component analysis the only data that could be quantified was whether or not the therapy exercises were adapted (yes/no) in response to the PWA's performance.

Key informants felt that it was important to measure what steps were selected and why (i.e. justification for tailoring). This was documented on the Therapy Planning Form and described in the process evaluation, but for the purpose of this analysis it is necessary to quantify this variable. The Therapy Planning Form was assessed for sense (by an SLT with expertise in the StepByStep approach) and for completion (by the author). Sense was only scored for a sub-sample of participants (one participant per site) so could not be included in this analysis, as such the completion score was used. Completion is only a proxy for 'what sequence of steps are selected and why' (the variable identified by key informants). The Therapy Planning Form assessment of completion was scored on a three point scale (0= no form or less than 50% complete; 1= more than 50% complete and some rationale provided; 2= 100% complete and some rationale provided for every step) with a higher score indicating that therapists had spent time documenting their choice of exercises and justifying how exercises had been tailored. Only one Therapy Planning Form scored 0 as no form was returned. For the purpose of this analysis this was treated as missing data. Consequently, the variable was treated as a binary categorical variable and the data was recoded (0= more than 50% complete and some rationale provided; 1=100% complete and some rationale provided for every step) with 0 as the reference category.

Data analysis

This analysis aimed to identify potential 'essential components' of the StepByStep approach to aphasia computer therapy by creating a multivariate model to explain the relationship between the dependent variable, change in word-finding ability, and multiple independent variables, aspects of intervention delivery/receipt (e.g. length of access to therapy).

In study two the key informants suggested a wide variety of aspects of intervention delivery/receipt that should be measured to indicate whether the intervention had been delivered/received as intended. To focus the investigation the author asked key informants to rate them by order of importance. The ten most highly rated aspects were selected as it was expected that 95 participants would be randomised to the intervention arm of the Big

CACTUS study and that would have approximately allowed the rule of thumb of one independent variable per ten events (i.e. participants) to have been applied to the regression analysis (Peduzzi et al, 1995). However, some aspects of the intervention key informants suggested to measure were categorical, thus creating more than one variable (e.g. content of therapy was translated into time spent on five different types of exercises). As a result there were too many independent variables for them to be entered directly into the model as originally intended. To adjust for this, an initial step was added wherein the relationship between the dependent variable and each independent variable was analysed separately (i.e. bivariate analyses) to establish which variables should go forward into the model. Bivariate analyses were conducted using a correlation matrix for continuous variables and independent samples t-tests for binary categorical variables. A trial and error approach was used to determine the selection criterion for inclusion in the multivariate model based on the level of statistical significance. A p-value cut-off of up to 0.25 has been recommended in the literature as more traditional levels (i.e. 0.05) can fail to identify important variables (Mikey & Greenland, 1989). A conservative p-value cut-off of 0.1 was selected for this study as it allowed a reasonable number of variables to be entered into the model without the model becoming oversaturated. This process of exploratory data analysis means that no specific hypothesis was being tested and the results must therefore be interpreted with caution.

Multivariate analysis has the benefit of investigating the relative influence of multiple independent variables on the dependent variable, rather than investigating each relationship in isolation (Campbell et al, 2007). A multiple linear regression was carried out including all independent variables associated with a change in word-finding ability in the bivariate analyses at the statistical significance level of $p < 0.1$. The model was adjusted for age and gender to ensure any findings were independent of these common confounders (Schneider et al, 2010). All analysis was carried out using SPSS v25. The four assumptions of multiple linear regression (normal distribution of residuals, homoscedasticity of residuals, linear relationship between variables and absence of multicollinearity) were checked (Campbell et al, 2007).

6.3 RESULTS

Participants

Data from all participants randomised to the intervention arm of the Big CACTUS trial with a baseline and six month word-finding assessment were included in the analysis (n=83). Fourteen participants did not complete the six month outcome measure due to death,

investigator decision and withdrawal of consent. Table 2 details the participant's demographic characteristics. Participant's word-finding improved from a mean score of 87.3/200 (SD=37.99) at baseline to a mean score of 120.14/200 (SD=45.79) six months after randomisation, as such the mean change in word-finding over the six month intervention period was 32.84 (SD=30.51).

Variables	N	Percentage
Gender		
Males	47	57
Females	36	43
Age groups		
≤55	23	28
56-65	21	25
66-75	22	26
≥76	17	21

Table 6.2. Participant's demographic characteristics

Bivariate results

A descriptive account of the findings for each aspect of intervention delivery and receipt has already been detailed in the process evaluation (chapter four). The results of the bivariate analysis exploring the relationship between change in word-finding score (from baseline to six month outcome measure) and the components of the intervention identified by key informants as important to measure are described in turn below and summarised in table 3.

The variable most highly correlated with change in word-finding ability at six months was the availability of the StepByStep software (e.g. having the opportunity to practise), which demonstrated a weak positive statistically significant correlation ($r=0.353$, $n=83$, $p=0.001$; see figure 6.3). The total amount of practice carried out by participants during the six month intervention period also showed a weak positive statistically significant correlation ($r=0.271$, $n=83$, $p=0.013$; see figure 6.4).

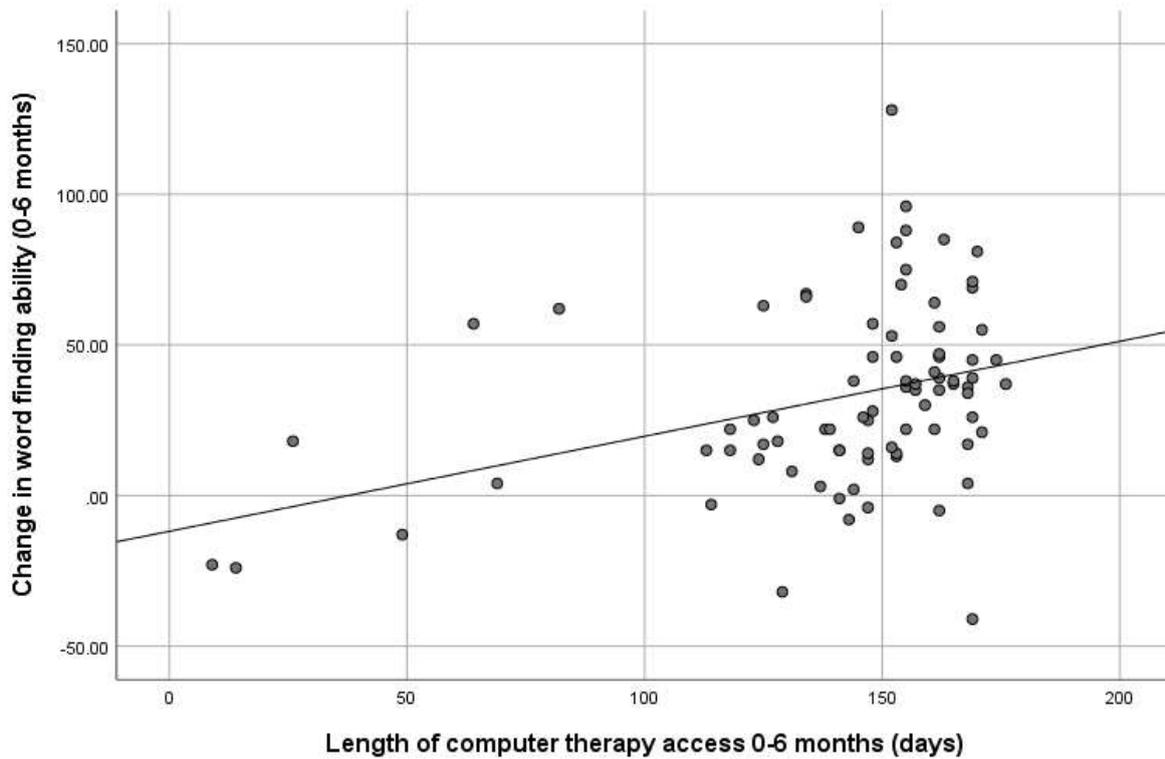


Figure 6.3. Scatterplot showing a weak positive relationship between availability of the StepByStep software and change in word-finding ability at six months

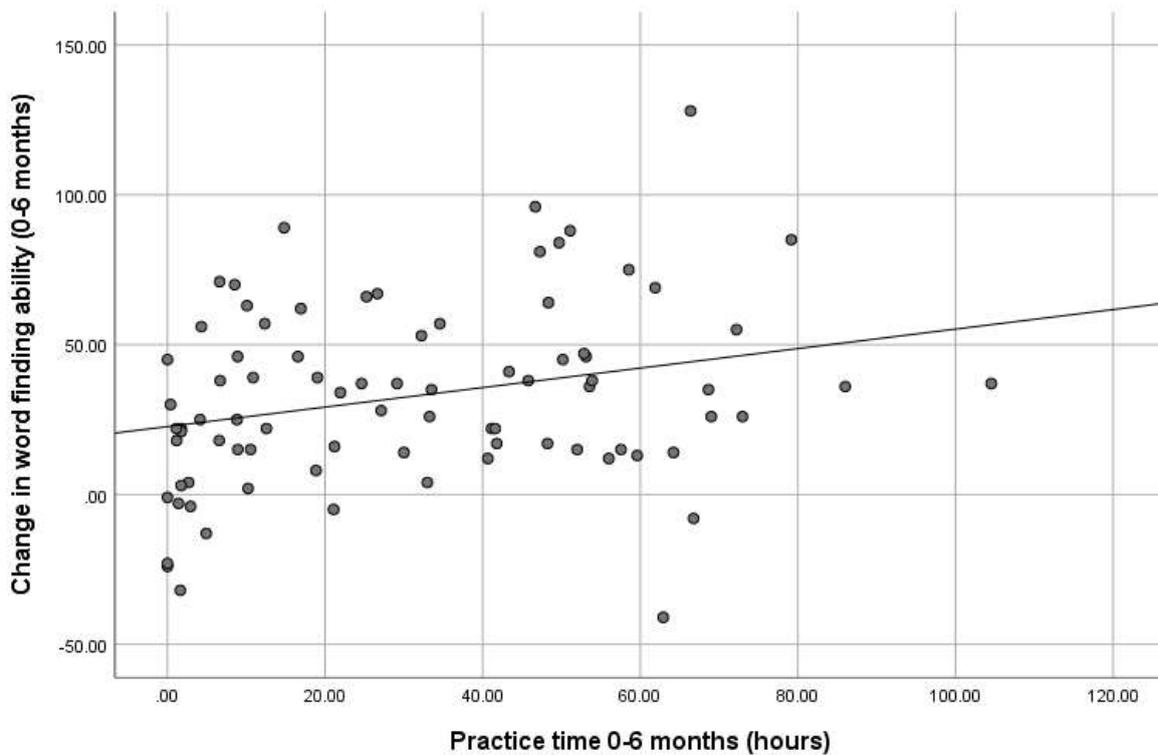


Figure 6.4. Scatterplot showing a weak positive relationship between the amount of computer therapy practice and change in word-finding ability at six months

Key informants in study two felt it was important to know the content of what people practised within the StepByStep software. For a description of the exercises see chapter one (page 34). The amount of time spent on two of the five therapy exercises demonstrated a weak positive statistically significant correlation with change in word-finding ability. The more time spent on 'naming words in functional sentences' exercises ($r=0.313$, $n=79$, $p=0.005$; see figure 6.5) and 'confrontation naming' exercises ($r=0.241$, $n=79$, $p=0.032$; see figure 6.6) the more word-finding ability improved over the six month intervention period. Time spent on the 'naming from a grid' exercises was positively correlated with improved word-finding at a level ($p<0.1$) to allow for inclusion in the multivariate analysis ($r=0.215$, $n=79$, $p=0.057$). The time spent on 'picture recognition/matching' exercises ($r=-0.029$, $n=79$, $p=0.799$) and 'using writing to cue naming' exercises ($r=0.103$, $n=79$, $p=0.367$) were not correlated with improved word-finding ability.

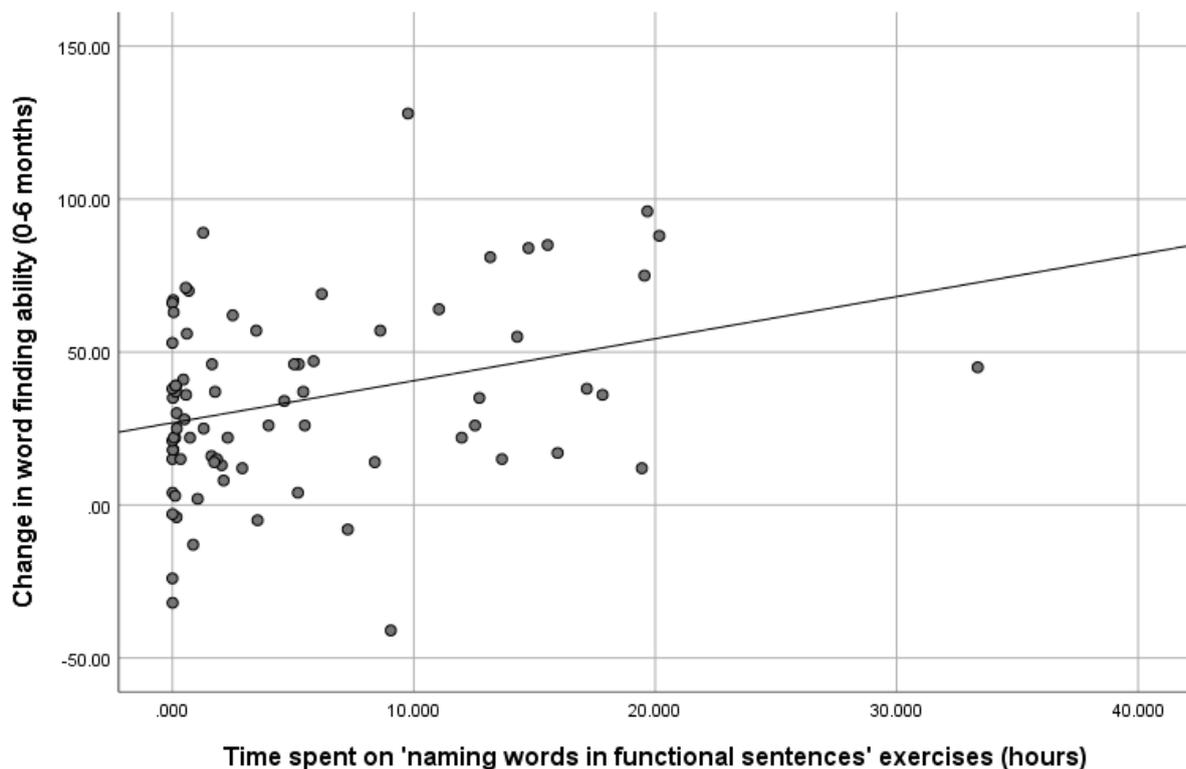


Figure 6.5. Scatterplot showing a weak positive relationship between time spent on naming words in functional sentences exercises and change in word-finding ability over six months

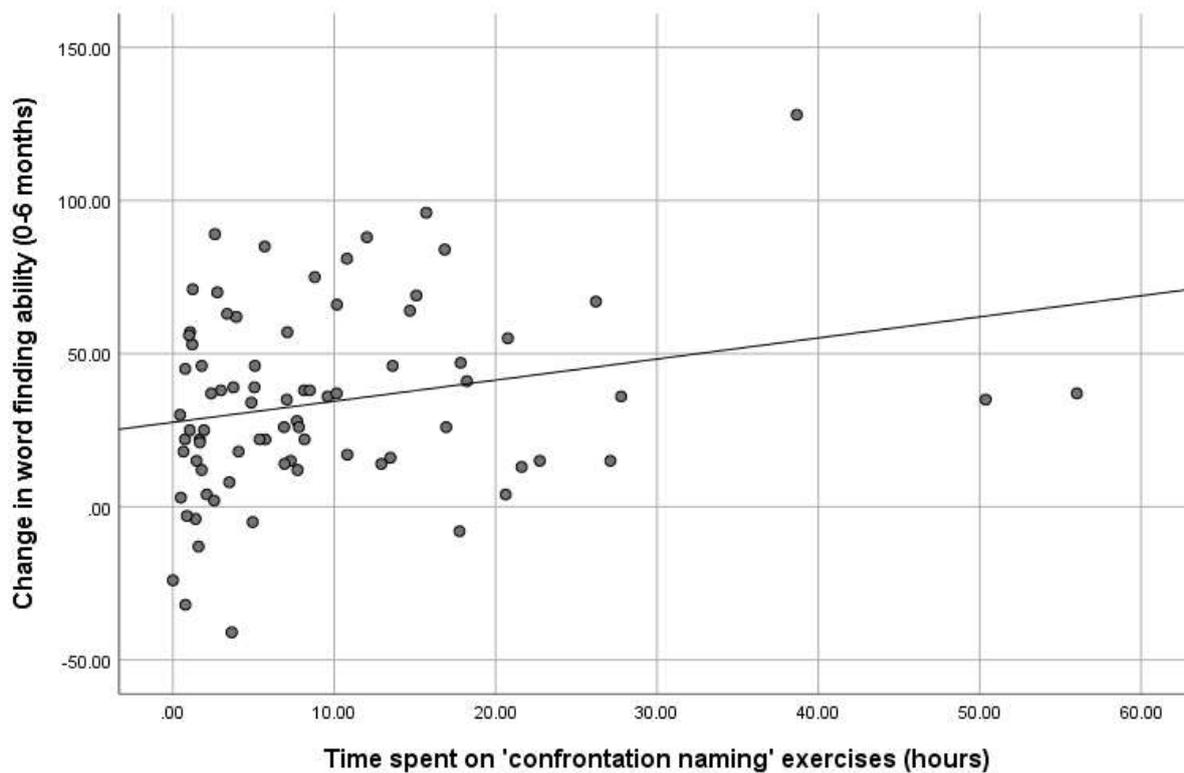


Figure 6.6. Scatterplot showing a weak positive relationship between time spent on confrontation naming exercises and change in word-finding ability over six months

There was a statistically significant difference between the mean change in word-finding ability of participants for whom the Therapy Planning Forms were 100% complete with some rationale provided for every discrete step ($M=37.42$; $SD=29.94$) and those for whom they were only 50% or more complete with only some rationale provided ($M=22.41$; $SD=29.7$) ($t=-2.139$, $n=82$, $p=0.035$). The results suggest that thorough documentation of therapists' rationale for tailoring of the therapy exercises was associated with improved word-finding.

The correlation between the treating therapists mean score on the lead therapist quiz and the participants change in word-finding ability indicated that there was no association between the two variables (see figure 6.7) and it did not meet the criteria for inclusion in the multivariate analysis ($r=-0.175$, $n=83$, $p=0.113$).

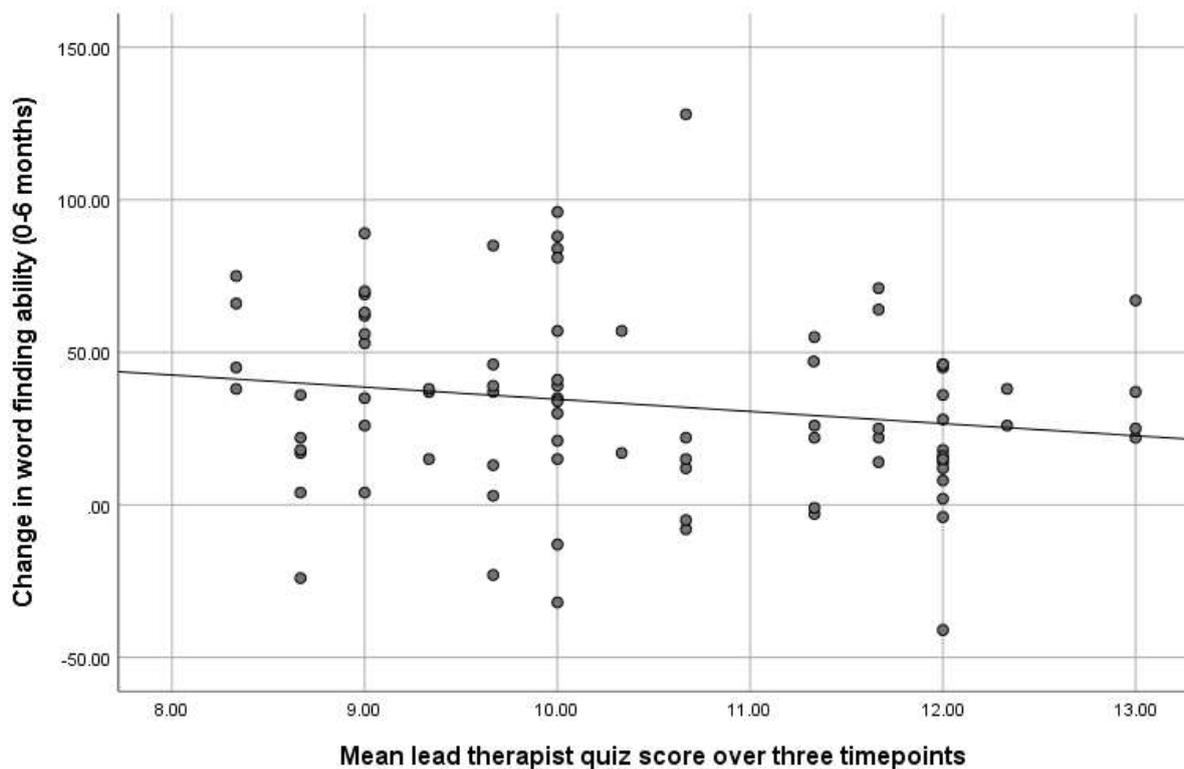


Figure 6.7. Scatterplot showing no association between the mean lead therapist quiz score and change in word-finding ability over six months

There was no statistically significant change in word-finding scores based on whether adaptations had ($M=37.43$, $SD=26.12$) or had not ($M=31.08$, $SD=32.07$) been made to the computer therapy exercises following initial therapy set-up and it did not meet the criteria for inclusion in the multivariate analyses ($t=-0.847$, $n=83$, $p=0.399$).

Four of the variables identified by key informants had too much missing data to have been included in the model, but the results of the bivariate analyses are reported below for completeness. There was a very weak positive, but not statistically significant, correlation between change in word-finding score and participants perception of how easy the StepByStep software was to use ($r=0.245$, $n=30$, $p=0.192$). There was no association between change in word-finding and participants self-reported motivation to practise the computer therapy ($r=-0.029$, $n=30$, $p=0.879$), participants' perception of the degree to which the words they were learning on the computer were personal to them ($r=0.138$, $n=32$, $p=0.450$) and volunteers composite score across all domains of the WAI-SRT ($r=0.183$, $n=19$, $p=0.453$).

Key component	Aspects of intervention delivery/receipt selected by key informants	Independent variables described as measured	Test statistic	P value	N
StepByStep software	Availability of the software (during the time the patient should have the software)	Number of days the therapy was available to the participant as documented by the treating therapist	r=0.353	0.001*	83
	Ease of use of the software	Patient reported ease of use of the software	r=0.245	0.192	30
Therapy set-up: tailoring and personalising	How skilled the person assessing the patient and setting up the software is	The treating therapists mean score on the Lead Therapist Quiz	r=-0.175	0.113	83
	What sequence of steps are selected and why (i.e. justification for tailoring)	Therapists completion of the Therapy Planning Form (e.g. recording therapy selected and justification for why)	t=-2.139	0.035*	82
	How much the words/photos have been personalised	Patient reported level of personalisation of vocabulary used in the computer therapy	r=0.138	0.450	32
Regular independent practice	Patient motivation	Patient reported level of motivation to practice	r=-0.029	0.879	30
	How much people practice	Practice time in the 6 months after randomisation (hours)	r=0.271	0.013*	83
	What people practice	Time spent on 'picture recognition/ matching' exercises (hours)	r=-0.029	0.799	79
		Time spent on 'confrontation naming' exercises (hours)	r=0.241	0.032*	79
		Time spent on 'using writing to cue naming' exercises (hours)	r=0.103	0.367	79
		Time spent on 'naming from a grid' exercises (hours)	r=0.215	0.057 [†]	79
		Time spent on 'naming words in functional sentences' exercises (hours)	r=0.313	0.005*	79
		Whether or not adaptations had been made to the computer therapy exercises as recorded on the Therapy Planning Form	t=-0.847	0.399	83
Supporting and monitoring practice	How the steps are adjusted or adapted in response to the PWA's performance	Composite score on WAI-SRT completed by therapy assistants or volunteers about their relationship with the participant	r=0.183	0.453	19
	How good the relationship is between the supporter (volunteer or assistant) and the PWA				

(*p<0.05, [†]p<0.1. Note. Both * and [†] eligible for inclusion in multiple linear regression model)

Table 6.3. Showing the aspects of intervention delivery/receipt associated with change in word-finding ability from baseline to six months

Multivariate model

Multiple linear regression was carried out to investigate the relationship between change in word-finding ability (baseline to six months) and all independent variables from the bivariate analysis with a significance level below 10%. This included: length of computer therapy access (days), degree of completion of the therapy planning form (indicating justification for tailoring), practice time (hours), time spent on confrontation naming exercises (hours), naming from grid exercises (hours) and naming words in functional sentences exercises (hours). The model was controlled for age and gender. Data from 78 participants with complete data for all variables were entered into the multivariate model.

Multicollinearity refers to high intercorrelations amongst the independent variables. The initial model violated the assumption for multicollinearity based on the more conservative rule of thumb of the tolerance being lower than 0.25 (Huber & Stephens, 1993) for the practice time variable (Tolerance=0.214). Multicollinearity was not unexpected as time spent practising the different exercises are sub-categories of total practice time and were therefore likely to be highly correlated. Consequently, total practice time was removed and the model was re-run.

The subsequent model identified two variables that were statistically significantly associated with change in word-finding: completion of the therapy planning form (indicating justification for tailoring; $p=0.041$) and the time spent on 'naming words in functional sentences' exercises ($p=0.038$). For every additional hour spent naming words in functional sentences there was a 1.103 increase in the word-finding score. If the Therapy Planning Form was *100% complete with some rationale provided for every step* (i.e. thorough justification for tailoring provided) participants scored an additional 13.839 marks on the word-finding assessment compared to those for whom the form was only *50% or more complete with some rationale provided*.

The three other aspects of intervention delivery included in the model were not found to be statistically significantly associated with change in word-finding ability: length of computer therapy access, time spent completing naming from grid exercises and confrontation naming exercises. Further details are reported in table 6.4.

Variable	Coefficient	P value	95% Confidence Interval (CI)	
			Lower CI	Upper CI
Length of computer therapy access (days)	0.195	0.080	-0.023	0.398
Time spent on naming word in functional sentences exercises (hours)	0.252*	0.038	0.063	2.143
Time spent on confrontation naming exercises (hours)	0.133	0.221	-0.233	0.990
Time spent on naming from grid exercises (hours)	0.004	0.974	-1.815	1.874
Degree of completion of the Therapy Planning Form (0=50% or more complete)	0.217*	0.041	0.551	27.128
Gender (0=male)	-0.059	0.598	-17.306	10.044
Age (years)	-0.234	0.040	-1.102	-0.026

* $p < 0.05$

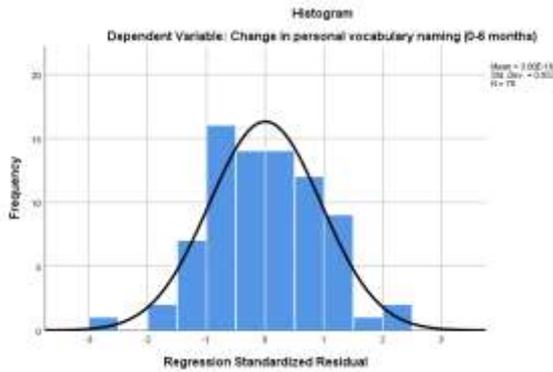
Table 6.4. Coefficients table with confidence intervals for the multiple linear regression model

The adjusted R^2 value was 0.207, so 20.7% of the variation in change in word-finding score can be explained by the model containing: length of computer therapy access (days), degree of completion of the therapy planning form, time spent on confrontation naming exercises (hours), naming from grid exercises (hours), naming words in functional sentences exercises (hours), gender and age. This demonstrates that the aspects of intervention delivery/receipt selected by key informants accounted for approximately a fifth of the variation in participant's word-finding improvement.

The data approximately met the assumptions for multiple linear regression. Multicollinearity was explored and one variable with a low tolerance (total practice time) was removed as described above. The scatterplots in figures 6.3-6.7 demonstrate linear relationships between the independent and dependent variable. The histogram shown in figure 6.8 indicates approximately normal distribution of residuals. The scatterplot of standardised predicted values versus standardised residuals⁶ shown in figure 6.8 demonstrates that the data approximately met the assumption of homoscedasticity (the points are equally distributed across all values of the independent variables).

⁶ *The standardised residual is the difference between the observed value and the predicted value (i.e. the residual) divided by its standard deviation (Campbell et al, 2007)*

Normality of residuals: residuals were approximately normally distributed



Homoscedasticity: no evidence of non-linearity or heteroscedasticity as the scatterplot does not have an obvious pattern

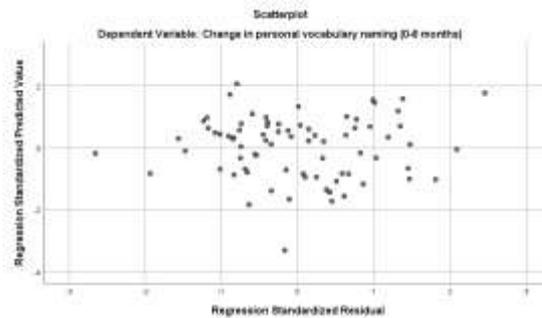


Figure 6.8. Histograms and scatterplots exploring statistical assumptions for the regression model

6.4 DISCUSSION

This study aimed to establish whether any components of the StepByStep approach to aphasia therapy were ‘essential’ to produce clinical improvement in word-finding ability in the Big CACTUS trial. The components of the intervention highlighted by this exploratory analysis as being ‘essential’ for the therapy to achieve its desired outcome included the time spent *practising* ‘naming words in functional sentences’ exercises and the therapist providing a thorough rationale for how they *tailored* the intervention to the needs of the individual PWA. Each of the components of the intervention are complex and comprise multiple sub-components (see intervention diagram, page 81) so only certain aspects of their delivery/receipt have been measured as recommended by key informants in chapter three. The term ‘essential’ component has been used throughout this chapter to follow the terminology used in the Conceptual Framework for Implementation Fidelity (CFIF; Carroll et al, 2007), however it is worth noting that these are components for which the quantity or quality of delivery of the component are tentatively associated with improved word-finding based on exploratory data analysis. Each component of the intervention identified in chapter three will now be discussed in turn.

StepByStep software

Two aspects of delivery/receipt relating to the StepByStep software itself were measured, including: perceived ease of use and the length of time it was available. The question relating to perceived ease of use received insufficient responses to be included in the multivariate analysis and whilst the limited data collected showed a trend toward those who found it easier to use also having improved word-finding ability, the finding was not statistically significant. The length of time the StepByStep software was available to participants was found to be associated with change in word-finding ability in the bivariate analysis. This is consistent with findings from the Cochrane Review of speech and language therapy for aphasia which found that providing therapy over a longer period may be beneficial (Brady et al, 2016). However, once length of computer therapy access was included in the multivariate model, adjusted for age and gender, the association was not found to be statistically significant.

Therapy set-up: tailoring and personalising

Three aspects of the intervention relating to therapy set-up were measured, including: what sequence of steps were selected and why (i.e. justification for tailoring), how much the words/photos have been personalised and how skilled the therapist assessing the PWA and setting up the software is. More rigorous documentation of tailoring was found to be associated with improved word-finding. Tailoring was documented on the Therapy Planning Form. The preferred measure for determining the quality of tailoring, was an expert SLTs score relating to whether the choice of exercises, prompts and cues made 'sense' based on the assessment results documented on the first page of the same form and the rationale provided by therapists. However, due to resource limitations, this measure was only completed for approximately 20% of participants so could not be included in the model. Instead, the degree of completion of the Therapy Planning Form was used as a proxy for the quality of the tailoring, but it is possible therapists could have completed the form comprehensively without having actually tailored the exercises to the individual following the principles of aphasia therapy. The question relating to participants' perception of the extent to which the words had been personalised had a low response rate and was not found to be associated with improved word-finding in the bivariate analysis. This is contrary to learning theory which suggests that the salience of practice stimuli positively influences outcomes (Raymer et al, 2008). However, perceived personalisation (i.e. the process of tailoring something to an individual's needs or preferences) and the salience of stimuli (i.e. a physical property of an object which makes it stand out) are somewhat different concepts, which may

explain this inconsistency. Performance on the lead therapist quiz was not found to be associated with change in word-finding ability. The quiz was designed by members of the Big CACTUS trial team who delivered the training on the intervention thus imparting some face validity. However, no validity testing was conducted to establish whether the quiz actually measured the intended construct of therapist skill. In retrospect, the use of a quiz rather than an assessment of therapy quality means the quiz was more likely evaluating therapist knowledge, rather than therapist skill. This has been acknowledged in terms of how the findings are described in the results section and accounts for the discrepancy in the use of the term ‘therapist skill’ in the method and ‘therapist knowledge’ in the results.

Regular independent practice

Three aspects of delivery/receipt relating to regular independent practice were measured: perceived motivation of PWA, how much people practised and what they practised. Bivariate analysis results found no relationship between perceived motivation and word-finding ability. Motivation was identified by key informants as a subcomponent of the regular independent practice component in chapter three, which was perceived to lead to more practice being carried out. However, this was not found to be the case in the quantitative analysis described in chapter five. Since the mechanism (i.e. increased practice) through which it was hypothesised that perceived motivation would improve word-finding ability was disproved, it is not surprising that no relationship was apparent between perceived motivation and word-finding ability.

The amount of time spent using the StepByStep computer therapy overall was associated with improved word-finding in the bivariate analysis. However, the variable had to be removed from the final regression model due to multicollinearity with more specific measures of time spent practising different types of exercises (total practice time was equal to the sum of time spent on the five exercise types hence the multicollinearity). The association between total practice time (i.e. dose) and improved word-finding ability is consistent with findings from the most recent Cochrane Review evaluating speech and language therapy for aphasia, which found that receiving therapy at a higher dose may be beneficial (Brady et al, 2016).

Experience-dependent neuroplasticity theory suggests that we learn what we practise including the ‘use it and improve it’ (training that drives a specific brain function can improve that function) and ‘specificity’ (the nature of the training dictates the nature of plasticity) principles (Kleim & Jones, 2008). It was therefore not surprising that the amount of time

spent on the two exercises that necessitated practising confrontation naming ('confrontation naming' and 'naming words in functional sentences') were the exercises associated with improved word-finding ability in the bivariate analysis, since the outcome measure was a confrontation naming assessment. However, only time spent on the 'naming words in functional sentences' exercises demonstrated a statistically significant association with improved word-finding ability in the multivariate analysis. Evidence from the neuroscience literature which suggests that it is beneficial to practise language in relevant action contexts (referred to as the behavioural relevance principle; Pulvermüller & Berthier, 2008) could provide a possible explanation for why 'naming words in functional sentences' (which sometimes included an action e.g. Where do you go to do your shopping? We go to the supermarket) was the only exercise associated with improved word-finding in the multivariate analysis. However, not all responses required an action (e.g. What is this? That is an oven). Pashek and Tompkins (2002) found that context influenced word retrieval with participants being able to retrieve more words in connected speech than in a confrontation naming tasks. Possible explanations for increased activation in connected speech proposed by the authors included sources of semantic facilitation being present within the utterance or syntactic priming influencing word retrieval (Pashek & Tompkins, 2002), both of which could apply to the 'naming words in functional sentences' exercises.

Approximately fifty percent of all practice time was spent on the 'using writing to cue naming' exercise (M=14 hours; chapter four, page 122) but it was not found to be associated with improved word-finding ability. Possible explanations for this include participants not realising that the purpose of spelling the word was to cue them to say the word or that the participants or the therapist tailoring the intervention chose to use it as a spelling exercise by not using or enabling the voice recognition feature. Multiple therapists documented hiding the voice recognition feature (see chapter four) and several PWA described their frustrations with voice recognition (chapter five), thus giving credence to this explanation. Time spent practising the 'picture recognition/matching' exercises was also not found to be associated with improved word-finding ability, however this would not necessarily have been expected as the primary aim of the exercise is for PWA to familiarise themselves with the items.

Supporting and monitoring use

Two aspects of delivery/receipt relating to supporting and monitoring use were measured, including how the steps were adjusted/adapted in response to the PWA's performance and how good the relationship was between the volunteer/assistant and the PWA. Neither aspect was found to be associated with word-finding. This could indicate the lack of importance of

this component of the intervention or it could be due to the aspects of delivery that were measured. In hindsight, it is arguable that it would have been beneficial to include the more objective measure of the amount of time the volunteers/assistants spent supporting participants in the model as well as the quality of the relationship measured by the WAI-SRT. Furthermore, whilst the WAI-SRT is a reliable and valid measure (Hatcher & Gillaspay, 2006) of the relationship between a therapist and patient, it has not been validated for use in this context (i.e. computer therapy support provided by assistant/volunteer). How the steps were adapted following the initial tailoring of the intervention was difficult to quantify, as such the variable used in this analysis was whether or not the steps had been adapted. Had the therapy been tailored appropriately in the first instance it would not have been necessary to make adaptations to the therapy, but the need for adaptation was not documented, only the adaptations made.

Clinical implications and future research

Complex interventions are not static and they do not operate within a vacuum. The authors of the CFIF state that one of the primary purposes of identifying 'essential' components of the intervention is to enable the intervention to be adapted to local context whilst remaining effective (Carroll et al, 2007). So the absence of components of the intervention identified as 'essential' would impact upon the ability of the intervention to achieve its desired goals. As such, the clinical recommendations to therapists implementing the StepByStep approach intervention in clinical practice would be to encourage PWA to focus on the exercises requiring the naming of words in functional sentences and have a thorough rationale for how the therapy is tailored to the individual PWA.

The StepByStep software itself is constantly being refined and updated (Steps Consulting Ltd website) and the identification of these 'essential' components will inform the next iteration of the software, and the training delivered to clinicians by the developers of the software. Future evaluation of fidelity to this intervention should include evaluation of the components identified as essential within this exploratory analysis to determine whether the intervention has been delivered faithfully. This would enable more rigorous a priori hypothesis testing and allow for future meta-analysis of the components associated with improved word-finding ability.

The multivariate model including length of therapy access, degree of documentation of tailoring, time spent on confrontation naming exercises, naming from grid exercises, naming words in functional sentences exercises, gender and age accounted for approximate twenty

percent of the variation in word-finding ability, thus demonstrating that many other factors impact change in word-finding ability. Possible factors might include individual differences, such as aphasia severity (Palmer et al, in press) or lesion size (Thye & Mirman, 2018), wider contextual factors, such as social support, or components of the intervention or mechanisms of action that were not measured within this study. Future research could develop a more comprehensive model to account for improvement in word-finding incorporating individual differences, such as those described above, as well as aspects of intervention delivery.

Exploratory data analysis was an appropriate strategy given the lack of prior knowledge about which components of the StepByStep approach intervention might be associated with clinical gains. However, future research could use this information about the proposed 'essential' components as a basis for more structured hypothesis testing to allow for more robust claims to be made from their findings. If more studies of similar interventions, such as the TACTUS therapy app (Stark & Warburton, 2018), are carried out in the future it would be beneficial to carry out a component analysis using meta-analysis techniques. This would allow exploration of the outcomes of different studies that have delivered similar interventions in slightly different ways, to establish whether the essential components remain the same across different samples and are therefore generalisable (Sutcliffe et al, 2015).

Limitations

A preferred method for this type of research would have been to review data from multiple studies which delivered the intervention slightly differently, in order to compare the presence or absence of different components, however, there are few trials of computer word-finding therapy and none on the same scale. Bivariate analysis to determine factors for inclusion in a multivariate model increases the chance of a type I error (false positive) due to overfitting of the model, but it was employed because it is still deemed to be preferable to using an automated regression function, such as Stepwise regression, due to the increased transparency of the method (Babyak, 2004).

Incomplete data for four of the measures might have impacted upon the conclusions drawn. It is possible that missing data relating to motivation, ease of use, and personalisation was not missing at random as the questionnaire needed to be completed by the individual or their carer and returned by post which might have been more difficult for severely impaired participants or those with multiple post-stroke impairments. Furthermore, incomplete WAI-SRT data might have been more likely if the volunteer/assistant was less engaged with trial activities or with the treating therapist, which might also have impacted upon their working alliance with the participant.

Several aspects of intervention delivery/receipt were measured using novel tools developed for the purpose of evaluating the fidelity of the StepByStep approach to aphasia computer therapy that were not validated, including: the lead therapist quiz, therapy planning form and questions about motivation, ease of use and personalisation. It is widely acknowledged that there is a lack of validated measures of fidelity in part due to the need for the measures to be tailored to specific interventions (Mowbray et al, 2003; Schoenwald et al, 2011). The lead therapist quiz was intended to evaluate therapist skill, but as previously discussed it was more likely evaluating therapist knowledge, however given the lack of validity testing it could have failed to measure any relevant construct. Therapist skill is typically evaluated through a video recording of a therapy session using a checklist to determine whether particular behaviours are performed (e.g. Thijssen et al, 2017). This method was not applicable in this context as there were no specific behaviours the therapist was expected to exhibit and a significant proportion of the therapist input was spent alone tailoring the computer therapy. An alternative measure of therapist skill would have been to use the score provided by the expert SLT who rated the extent to which they understood the rationale provided on the Therapy Planning Form for how the therapy was tailored according to the assessment results. However, only a sub-sample of participant's Therapy Planning Forms were scored by the expert SLT, due to resource limitations, thus preventing inclusion in this analysis. Similarly the 'sense' score would have been a better measure of 'what sequence of steps were selected and why (e.g. justification for tailoring)', but it could not be used for the same reason, so the score provided by the author relating to the completion of the Therapy Planning Form had to be used instead. The measures of perceived motivation, ease of use and personalisation have been critiqued elsewhere (chapter four, page 152).

Another limitation of the study was that we only explored the relationship between the delivery of intervention components and one of the desired outcomes of the intervention (word-finding). As described in the introduction there was no significant difference between trial groups on the co-primary outcome of conversation rated using the TOMS activity scale (Enderby et al, 2013) in the Big CACTUS trial and concerns have been raised regarding the sensitivity of the TOMS (John et al, 2011). There was, however, a secondary measure of the impact of word-finding therapy on functional communication (counting trained words used in conversation) and it would be interesting to explore the relationship between this outcome and the aspects of intervention delivery and receipt explored in this chapter.

Conclusion

Whilst the findings of this chapter must be interpreted with caution due to the exploratory nature of the analysis, the components of the intervention that appear to be 'essential' for improved word-finding are: rigorous tailoring of the computer therapy exercises by the SLT and PWA spending more time practising the 'naming words in functional sentences' exercise. When time is limited SLTs have to prioritise the time spent on different therapeutic activities, these findings demonstrate the value of spending time tailoring computer therapy exercises. Therapists should also encourage PWA to work through all of the exercises on StepByStep software to ensure they reach the 'naming words in functional sentences' exercise.

Chapter Seven: Discussion

Each of the chapters presenting findings (chapters two to six) have included a discussion comprising: 1) interpretation of the findings in the context of previous research, 2) strengths and limitations, and 3) implications of the research for subsequent studies within the thesis, clinical practice or future research, as appropriate. To minimise repetition, after summarising the findings to demonstrate how each objective has been addressed, this chapter will concentrate on the meaning of the study's findings as a whole. This will involve synthesising the results of later chapters and discussing key themes arising from the thesis. Subsequently, clinical implications and suggestions for intervention refinement will be discussed, followed by the strengths and limitations of the thesis as a whole and recommendations for future research.

7.1 SUMMARY OF FINDINGS

The overall aim of this thesis was to evaluate the intervention fidelity of aphasia computer therapy delivered within the Big CACTUS trial. Fidelity to the StepByStep approach was evaluated by addressing the five objectives described below.

- 1) Methods used to evaluate intervention fidelity in the field of stroke rehabilitation will be reviewed (study one; chapter two)

Reviewing the stroke rehabilitation literature identified a wide variety of fidelity evaluation methods, including self-report forms, direct observation, video observation, audio observation, electronic data capture from intervention software and qualitative interviews. The common thread was that the methods used to evaluate fidelity were specific to each intervention, therefore the measures chosen to evaluate fidelity in the Big CACTUS trial were tailored to the StepByStep approach. The review also identified a lack of clarity in how judgements were made regarding the degree of fidelity with which an intervention had been delivered. Consequently, a transparent scoring system was applied to the fidelity evaluation in the Big CACTUS trial to ensure transparency.

2) Key components of the StepByStep approach to aphasia computer therapy will be described and methods of measurement explored (study two; chapter three)

Components of the StepByStep approach were described by key informants. Four key components were identified, including: the StepByStep software; therapy set-up (tailoring and personalising); regular independent practice; and supporting and monitoring use. The four key components were used to structure the fidelity evaluation, thus enabling the evaluation to be tailored to the intervention. The ten most important aspects of the intervention to measure were identified along with possible methods for doing so. The components perceived to be most important to measure comprised aspects of 1) adherence (how much people practised; what people practised; availability of the software), 2) quality of delivery (therapist skill; how the exercises are tailored; how the exercises are adapted; the relationship between the supporter and the Person With Aphasia (PWA)), and 3) participant responsiveness (motivation to practise, ease of use of software and degree of personalisation of the vocabulary). These aspects were measured in the process evaluation and formed the basis for the component analysis.

3) Intervention fidelity to the StepByStep approach to aphasia computer therapy in the Big CACTUS trial will be evaluated (study three; chapter four)

The process evaluation found that the intervention was delivered with moderate to high fidelity overall. The StepByStep software component was delivered with very high fidelity, the therapy set-up and supporting and monitoring use components were delivered with high fidelity and the regular independent practice component was received with moderate fidelity. Therapists spent more time than expected setting-up the therapy, whereas volunteers/assistants spent less time than expected. In particular, volunteers/assistants spent an average of only 45 minutes on activities designed to encourage PWA to use the words they were learning on the computer in everyday conversation. This is particularly important because the Big CACTUS trial found word-finding improved, but this did not translate to improved functional communication.

4) Factors associated with adherence to aphasia computer therapy practice will be explored (study four; chapter five)

The factors associated with adherence (one of the key elements of fidelity) were explored using qualitative interviews and secondary data analysis. The findings from the two data sources were synthesised using the COM-B system (Michie et al, 2011)

to frame the integration. Factors associated with the PWA's capability to adhere to aphasia computer therapy practice included: cognitive impairment, fatigue, level of understanding of their own condition, knowledge of the intervention and supporters help to develop the skills required to use the computer therapy. Additionally, more time having elapsed post-stroke was associated with greater adherence. Factors that positively influenced the PWA's opportunity to practice included: having access to the computer therapy for longer, receiving more support from therapists and volunteers/assistants, and specific features of the software (home-based therapy and personalisation). Conversely factors that negatively influenced the PWA's opportunity to practice included computer therapy software and hardware problems, as well as barriers to practice (such as illness and having other commitments). Motivational factors that influenced adherence to aphasia computer therapy practice, identified only from the qualitative interviews comprised PWA's beliefs about their own capability, beliefs about consequences, stability of intentions, reinforcement (via feedback from software), emotion, personality and habit.

- 5) Components of the StepByStep approach to aphasia therapy that are 'essential' to produce the desired outcome will be identified (study five; chapter six)

Exploratory data analysis indicated that the components of the intervention that appeared to be 'essential' for improved word-finding are: PWA spending more time practising 'naming words in functional sentences' exercises and rigorous tailoring of the computer therapy exercises by SLTs.

7.2 SYNTHESISING FINDINGS ACROSS STUDIES

As a mixed methods thesis with multiple studies and data collection strategies it was described how the sequential exploratory design enabled the findings from study one and two to inform the design of studies three, four and five. Furthermore, the concurrent triangulation design adopted in study four included a convergence coding matrix to enable the qualitative and quantitative findings to be synthesised. What has not yet been synthesised are the findings from studies three, four and five which explored related aspects of fidelity and whose findings have the potential to influence the interpretation of one another. The findings will be synthesised below in two sections.

Synthesising the findings of the process evaluation (study three) and exploration of adherence (study four)

The process evaluation (study three) measured each of the key components individually, however the in-depth exploration of adherence (study four) demonstrated the interconnectedness of the key components. Three of the quantitative factors found to be associated with the amount of independent practice were measures of the dose of aspects of other key components (SLT support, volunteer/assistant support and duration of access to the StepByStep software). This echoes the StepByStep approach diagram from study two (page 81) which illustrated how key informants perceived the components to impact upon one another. The findings from the process evaluation and the exploration of adherence demonstrated convergence, with qualitative findings providing additional explanation for the predominantly quantitative process evaluation findings. For example, the process evaluation highlighted the reasons for delays in accessing the StepByStep software documenting the technological problems reported by therapists, whereas the qualitative interviews described the frustration experienced by the PWA and how it resulted in lower amounts of practice at an individual level.

Synthesising the findings of the process evaluation (study three) and component analysis (study five)

The process evaluation placed equal weight on delivering each of the key components of the intervention. Consequently, it is possible that fidelity was measured for components that are not actually necessary to produce the desired outcome. The component analysis subsequently explored which of the components are associated with the desired outcome, thus suggesting that delivery of certain components or sub-components might be more important than others. Whilst the components cannot be viewed as discrete entities, due to the interconnectedness of the components (described in study two and study four), the fidelity of those components found to be associated with improved word-finding might be of greater relevance. Fidelity of the 'essential' components is considered below.

The therapist providing a more thorough rationale for how they tailored the intervention was associated with improved word-finding and it was delivered with high fidelity in the Big CACTUS trial. Time spent carrying out regular independent practice of the 'naming words in functional sentences' exercise was another 'essential' component, however this one is slightly more complicated as this is only one subcomponent of the regular independent practice component and no recommendations were provided about the amount of time that should be spent on each exercise (i.e. content of practice). Bivariate analyses indicated that the total amount of practice was associated with improved word-finding, as well as time

spent on three of the exercises: 'confrontation naming exercises', 'naming from grid exercises' and 'naming words in functional sentences exercises'. Interestingly these are all of the exercises that necessitate confrontation naming (e.g. practising word-finding). Multicollinearity meant that the total amount of practice had to be removed from the multivariate model and only 'naming words in functional sentences' was significantly associated with improved word-finding in the multivariate model. The average amount of time spent on the 'naming words in functional sentences' exercise (median 1.6 hours) was a small proportion of the total practice time. The most practised exercise on average was 'using writing to cue naming' (median 9.1 hours), which was not found to be associated with improved word-finding. By synthesising these two findings it is possible to demonstrate that much of the regular independent practice carried out as part of the Big CACTUS trial was spent practising a therapy exercise that had little impact on the word-finding outcome. It would be interesting to understand whether PWA were using this as a spelling task or whether they were actually using writing to cue naming (e.g. typing to try and cue verbal word retrieval) as intended, and why 'using writing to cue naming' was the most practised exercise. For example, participants might have wanted to improve their spelling, although that was not the aim of the study, demonstrating a tension between the clinical realities of PWA requiring treatment for multiple complex impairments and delivering a focused intervention as part of a RCT. Alternatively, it might have been that the 'using writing to cue naming' exercise was more enjoyable (feedback on spelling accuracy was consistent) or that this exercise was copied (i.e. duplicated) more during the tailoring process (there are more tailoring options for this step).

Whilst identification of the components associated with improved word-finding ability might help to inform the design of future fidelity evaluation of aphasia computer therapy it is important to remember that the interconnectedness of the components means that it is still necessary to evaluate intervention fidelity holistically to gain a complete understanding of how the intervention was delivered and received. Furthermore, the component analysis only explored the relationship between components of the intervention and word-finding ability, but the overall goal of aphasia therapy is to improve functional communication and components that might assist with this were not explored in this study. As such, it would not be advisable to limit any further fidelity evaluation to only those components found to be associated with improved word-finding.

7.3 DEVELOPMENT OF THE FIELD OF FIDELITY IN APHASIA AND STROKE REHABILITATION RESEARCH

Recognition of the importance of evaluating fidelity has grown in recent years. This was exemplified in the updated literature review in 2019, which showed a marked increase in the number of studies published in the stroke rehabilitation literature since the original review in 2016. A similar increase was seen in fidelity reporting in the field of aphasia treatment studies between the review carried out by Hinckley & Douglas in 2013 and Brogan and colleagues in 2019. Increased reporting of fidelity might be a response to increased use of the TIDieR template for intervention description (Hoffman et al, 2014) and the recent recommendations from the Stroke Recovery and Rehabilitation Roundtable (Walker et al, 2017). Whilst recognition of the importance of fidelity evaluation has grown, there is still a long way to go before fidelity could be perceived to be a highly valued element of RCTs of complex interventions in the fields of both aphasia and stroke rehabilitation research. For example, despite the Big CACTUS trial having a comprehensive fidelity evaluation the editors of the Lancet Neurology requested the data from the fidelity evaluation be removed from the main results paper of the Big CACTUS trial, suggesting it was more appropriately placed in the supplementary material (Palmer et al, 2019). It would be unacceptable to report the findings of a RCT and not state how and when the outcome was measured, but measuring and reporting the cause of the outcome (i.e. the intervention), appears to be perceived by editors to be of lower importance. This raises questions about how best to report the data from fidelity evaluations. For example, should fidelity evaluation data be presented in the main results paper? Or does the complexity of such an evaluation mean that it needs to be published in a separate article?

7.4 METHODOLOGICAL CONSIDERATIONS FOR FIDELITY RESEARCH

Fidelity evaluations are typically carried out alongside RCTs, which are trying to determine whether or not the intervention works. It is good practice to state whether a trial is pragmatic (evaluating the effectiveness of the intervention in 'real-world conditions') or explanatory (evaluating the efficacy of the intervention in ideal conditions) in purpose. The PRECIS-2 tool has been developed to help researchers to determine where on the exploratory-pragmatic continuum their trial is positioned (Loudon et al, 2015). The Big CACTUS trial was positioned toward the pragmatic end of the continuum (Palmer et al, 2019). The item from PRECIS-2 relevant to fidelity evaluation asks, "how different is the flexibility in how participants are monitored and encouraged to adhere to the intervention from the flexibility anticipated in usual care?" (Loudon et al, 2015). It is proposed that a trial would score as highly pragmatic

if no special measures were in place to enforce or enhance adherence beyond the encouragement available in usual care. Whilst fidelity (including multiple measures of adherence) was monitored within the Big CACTUS trial, none of the fidelity data was used to encourage participants to adhere to the therapy beyond what would be provided in usual care (e.g. volunteer/assistant monitoring practice on the StepByStep software calendar and encouraging practice). As a result the adherence data collected provides an indication of how likely PWA are to engage with the StepByStep approach in routine clinical practice. There has been limited discussion of the interplay between the pragmatic-explanatory trial continuum and fidelity evaluation/enhancement (Miller & Rollnick, 2014). The NIH-BCC framework, which has been highly influential in fidelity research, strongly emphasises the importance of fidelity enhancement (Bellg et al, 2004) which is more appropriately applied to an explanatory trial. Whilst the authors do recognise that it might not be “feasible to use all desirable treatment fidelity strategies”, they do not acknowledge the negative impact strategies to enhance fidelity could have on external validity in terms of reducing the replicability of the findings if the intervention were delivered in clinical practice, where resource intensive fidelity enhancement strategies from research cannot necessarily be implemented. In contrast, the CFIF, which has guided this fidelity evaluation, includes facilitation strategies (i.e. treatment manual/provider training/feedback) as one of the potential moderators of adherence (Carroll et al, 2007). This encourages researchers to consider these factors, but primarily emphasises evaluating fidelity rather than enhancing it, which is consistent with the purpose of a pragmatic trial.

One tension that arose in the design of the fidelity evaluation was the fact that as a pragmatic trial of a complex, tailored intervention there was a lot of flexibility in how the intervention could be delivered. Whilst the intervention was clearly defined in the Big CACTUS protocol (Palmer et al, 2017) and treatment manual (Palmer, 2015), there was no criteria of activities or behaviours that could be scored according to a checklist, as is often carried out for psychological interventions (i.e. cognitive behavioural therapy; Hadjistavropoulos et al, 2018). Also, as a self-managed intervention, in which much of the therapy was received when the participant was working independently, assessing the therapists behaviour feels much less relevant as their role is less central to the therapy than, for example, a one-to-one psychological intervention. Other researchers exploring fidelity of technology based behavioural interventions have proposed a fidelity framework incorporating the Technology Acceptance Model (perceived usefulness/ ease of use/ attitude toward use/ intention to use) (Dabbs et al, 2011). However, whilst the model included technology acceptance it did not outline any elements of fidelity or consider how any factors beyond technology could influence fidelity.

7.5 CONCEPTUAL FRAMEWORK FOR IMPLEMENTATION FIDELITY

The CFIF was chosen to inform the evaluation of intervention fidelity described within this thesis because it acknowledges that the elements of fidelity are not discrete and it proposes how the elements interact with one another (i.e. moderators influence adherence, which in turn influences outcome) (Carroll et al 2007). The CFIF was originally designed to support implementation research, but has subsequently been evaluated in a research context (Hasson et al, 2010). Its origins make it more compatible with a pragmatic RCT like Big CACTUS, in which the intervention was being delivered by community SLT teams around the UK with minimal input from the central trial team. A recent literature review of treatment fidelity in aphasia RCTs proposed that the NIH-BCC framework (Bellg et al, 2004) was the gold standard for addressing treatment fidelity in research, which implies many aphasia trials are exploratory rather than pragmatic. I would instead agree with the recommendations from the Stroke Recovery and Rehabilitation Roundtable (Walker et al, 2017) that the use of a fidelity framework at the design stage may encourage researchers to consider which elements of fidelity are most important to monitor during the trial. The CFIF (Carroll et al, 2007) was a better fit for a flexibly delivered, self-managed intervention being evaluated within a pragmatic RCT, than the more linear NIH-BCC framework (Bellg et al, 2004) which emphasises the enhancement of each element of fidelity.

The other advantage of the CFIF over the NIH-BCC framework, was that it included a mechanism for identifying which components of the intervention are 'essential' for producing the desired outcome. Carroll et al (2007) proposed that component analysis could be carried out using fidelity and outcome data from different studies of the same intervention. The Big CACTUS trial is the only large scale evaluation of the StepByStep approach to aphasia computer therapy. As such it was decided to carry out a component analysis using data from just this trial. There are few examples of fidelity evaluation being used to try and identify 'essential components' of an intervention (Abry et al, 2015; Hermens et al, 2001). Abry and colleagues (2015) identified one potential 'essential component' (which they termed an active ingredient) in an educational intervention by investigating the relationship between educational achievement and fidelity ratings across core components. It was concluded that the ability to carry out such analysis was one of the benefits of measuring fidelity separately across the different intervention components, rather than the more traditional approach of providing one composite fidelity score (Abry et al, 2015). Similarly, if the StepByStep approach to aphasia computer therapy had been measured using a checklist with a composite score it would not have been possible to conduct a component analysis to determine which components were associated with improved word-finding.

7.6 NEUROPLASTICITY AND DOSE

As described in the background (page 25), neuroplasticity is one of the key theories underpinning language recovery (Kleim & Jones, 2008). The content of practice (i.e. time spent on five different types of therapy exercises) was included in the component analysis in chapter six. Spending more time practising exercises that necessitated confrontation naming was found to be associated with improved word-finding. Whereas no relationship was found between the amount of time spent on the exercises that do not require confrontation naming and improved word-finding. This supports the 'specificity' neuroplasticity principle, which suggests that the nature of the training experience dictates the nature of plasticity (Kleim & Jones, 2008).

The debate around the importance of intensity, one of the neuroplasticity principles, or dose was described in the background. In chapter six, the bivariate analysis indicated that carrying out more practice was associated with improved word-finding, which to some extent supports the 'intensity matters' neuroplasticity principle (intensity was not defined by Kleim & Jones (2008) and could be viewed as tantamount to dose). The Cochrane Review for aphasia therapy found that functional communication was significantly better when PWA received interventions at a higher intensity, higher dose or over a longer period (Brady et al, 2016). Based on current use of the term intensive practice (minimum four hours per week indicating intensive therapy in the Cochrane Review; Brady et al, 2016), the aphasia computer therapy in the Big CACTUS trial (approximately one hour per week) could not be described as an intensive therapy. However, because the intervention was delivered over a long duration (approximately four months) in the Big CACTUS trial the dose was still relatively high (average 26 hours; similar to the minimum 27 hours classed as a high dose in the Cochrane Review; Brady et al, 2016). Unlike the finding from the Cochrane Review that more participants dropped out of higher dose interventions (Brady et al, 2016), the Big CACTUS trial did not have greater attrition in the intervention group, most likely because as a self-managed intervention the participants chose how much independent computer therapy practice to carry out (Palmer et al, 2019).

According to Cherney (2012) optimal treatment intensity has not been established for any aphasia therapies. The Big CACTUS protocol (Palmer et al, 2017) and therapy manual (Palmer, 2015) recommend PWA use the computer therapy for 20-30 minutes every day for six months, but no direction was provided regarding a maximum amount of practice. Consequently, one of the key assumptions underpinning this thesis was that more therapy would result in improved outcomes. Cherney (2012) suggests that the notion that 'more is better' is overly simplistic and not supported by the evidence. Whilst the total amount of

computer therapy practice was found to be associated with word-finding ability in the bivariate analysis, it was not included in the multivariate analysis due to multicollinearity, with time spent on different therapy exercises included instead. Time spent on 'naming words in functional sentences' exercises was the only measure of dose found to be associated with improved word-finding in multivariate analysis. Measuring the amount of time spent using specific therapy exercises is a less blunt measure compared to total therapy time. However, it has been suggested that the key to understanding optimal intensity/dose is to overcome the issue of defining intensity (Baker, 2012). In order to achieve this it has been proposed that one must not only report the dose, dose frequency and total intervention duration in order to enable the cumulative intervention intensity to be calculated, but one must also establish dose form, which is the "typical task or activity within which the teaching episodes are delivered" (Warren et al, 2007). In the StepByStep approach to aphasia computer therapy the teaching episodes are delivered in the form of computer therapy exercises. It would have been interesting to explore the impact of including the number of teaching episodes PWA completed in the analysis. This information could potentially be extracted from the key files, however count data was recorded by day for each participant so collating the information for all of the participants would have been laborious and was beyond the scope of this study.

It is possible that other individual factors might impact on the relationship between dose and outcome. For example, the relationship between the amount of independent practice and word-finding ability was reported stratified by severity (Palmer et al, 2019; supplementary material, page 59). Those with severe word-finding difficulties appeared to benefit more from greater amounts of practice, whereas benefits for those with mild/moderate word-finding difficulties appeared to diminish beyond 26 hours of practice. If factors, such as severity, impact upon the optimal dose then it might be that optimal dose depends on the characteristics of the PWA and a generic recommendation about optimal intensity would not be beneficial as the intervention dose/intensity needs to be tailored to the needs of the individual.

The Big CACTUS trial found that the StepByStep approach to aphasia computer therapy improved word-finding, but there was no difference in functional communication ability across groups (Palmer et al, 2019). A commentary on the study suggested that what may have been needed to allow the clinical gains to generalise into functional communication is for PWA to receive a greater dose (Flöel, 2019). This recommendation disregards the 'specificity' neuroplasticity principle (Kleim & Jones, 2008). If the nature of the training experience (naming words on a computer) dictates the nature of plasticity, why would increasing the amount of time naming words on a computer help people to use more words

in functional conversation? Additional secondary analysis of Big CACTUS data could explore this further by investigating whether PWA who carried out more computer therapy practice improved more on functional communication measures.

7.7 TECHNOLOGY AND APHASIA

Research into the use of technology for aphasia rehabilitation has increased in recent years. Implicit in much of this research is the assumption that PWA are able to engage with computer devices, however some have explored *how* PWA engage with technology. A review grouped the barriers affecting technology use for PWA into those relating to the health condition, healthcare services and the nature of the technology (Brandenburg et al, 2013). As well as the obvious impact of language difficulties, such as the need for reading and writing for many technology-based interactions, PWA post-stroke also commonly have other cognitive, motor or visual deficits that can impact upon their use of technology (Brandenburg et al, 2013). Despite the fact that the StepByStep software was designed specifically for aphasia rehabilitation, with input from PWA and their carers, participants in the Big CACTUS trial only perceived that it was moderately easy to use (chapter four). However, it is important to note that ease of use might be impacted upon by the severity of aphasia as the trial included a broad spectrum of aphasia severities (Palmer et al, 2019). The amount of input and support offered for different communication aids and software programs from healthcare services varies depending on the type of technology and how the services are accessed. Software or apps used on people's own technological devices are thought to be those least supported by healthcare services (Brandenburg et al, 2013). A recent study explored the process of delivering bespoke computer training courses for PWA and found that it improved their self-rated ability on a range of computer skills and helped to overcome barriers to technology use (Kelly et al, 2016). This echoes the finding from chapter five that more support from SLTs and assistants/volunteers was found to be associated with increased engagement with the StepByStep approach to aphasia computer therapy. Brandenburg and colleague's (2013) review also highlighted that the design and nature of the technology can impact upon adoption with factors including: screen size, privacy and security (i.e. password protection) and knowing which app or software might be relevant (Sarasohn-Kahn, 2010). Some have developed aphasia-friendly and accessible social exchange platforms where PWA can connect exclusively with other PWA, such as AphasiaWeb (Buhr et al, 2016). However, the same article describing the development of an aphasia specific platform also received input from PWA suggesting that it would also be valuable for there to be aphasia friendly interfaces for universal social networking platforms

through which they could contact their family and friends (Buhr et al, 2016). The StepByStep approach is an aphasia specific rehabilitation program, but qualitative interviews from the pilot study found that one of the benefits of the StepByStep approach was an increased engagement with technology more widely (Palmer et al, 2013); however, this was not explored as part of the Big CACTUS trial.

7.8 CLINICAL IMPLICATIONS

The findings of the exploration of adherence demonstrated that clinicians delivering aphasia computer therapy should consider the capability, opportunity and motivation of the individual when considering whether self-managed therapy is the most appropriate means of delivering therapy for that individual. Specific factors relating to the capability of the PWA to use the computer therapy included factors such as, cognitive impairment, level of understanding of their own condition, knowledge of the intervention and the role supporters can play in skill development. Furthermore, PWA might have more capability and opportunity to use the computer therapy once more time has passed since their stroke. Clinicians play a vital role in facilitating the opportunity to practise, which was as much about the need for support from SLTs and volunteers/assistants as it was about their role in facilitating access to the aphasia computer therapy for a long period. One of the key roles of the supporters was to provide technical support, which was required in order to overcome the technological issues that prevented access to the computer therapy highlighted in this study. Clinicians should also consider how the motivation of the PWA might influence their decision to practise, with potentially modifiable motivational factors including: creating shared goals and beliefs about the computer therapy, ensuring feedback on performance from the computer therapy is accurate (or removing the function) and helping the PWA to think of ways to incorporate computer practice into their daily routine. These findings could be used to inform how self-managed computer therapy interventions are delivered by SLTs more widely as many of the recommendations are not specific to the StepByStep approach.

Effective dissemination of evidence-based interventions, such as the StepByStep approach to aphasia therapy, assumes that they will be delivered with fidelity. However, recent research has recognised and explored the adaptations interventions undergo during the implementation process (Carvalho et al, 2013). The Big CACTUS trial demonstrated the effectiveness of the StepByStep approach to improve word-finding when delivered with moderate to high fidelity (Palmer et al, 2019). During uptake of the intervention it is possible that clinicians will make adaptations to the intervention by making slight alterations to how a component is delivered or by picking and choosing which components or sub-components of

the intervention to implement. The component analysis conducted as part of this doctoral research identified the components of the intervention associated with improved word finding. The analysis demonstrated that rigorous tailoring of the therapy exercises to the individuals need and the PWA spending more time practising the 'naming words in functional sentences' exercises were associated with improved word-finding. Conveying the findings of the component analysis to clinicians could provide guidance on delivering the components of the intervention that are most important to produce the desired outcome. One way to disseminate these findings to clinicians, beyond publishing the findings in an academic journal, could be to use the findings to update to the StepByStep approach therapy manual. See box 7.1 for a list of the clinical recommendations arising from this study.

Box 7.1: Clinical recommendations

In order to increase adherence to aphasia computer therapy practice:

- Consider factors relating to the capability of the PWA to use the computer therapy, including: cognitive impairment, level of understanding of their own condition, knowledge of the intervention and the role supporters can play in skill development.
- Offer aphasia computer therapy to PWA who had their stroke longer ago as they might have more capability and opportunity to use the computer therapy.
- Facilitate the opportunity to practise by making the therapy available for a long period of time, providing support to the PWA, and enabling volunteers/assistants to provide support. Timely support can help to overcome some of the technological issues that can prevent access to the computer therapy.
- Consider how the motivation of the PWA might influence their decision to practise, with potentially modifiable motivational factors including: creating shared goals and beliefs about the computer therapy, ensuring feedback on performance from the computer therapy is accurate (or hiding the function) and helping the PWA to think of ways to incorporate computer practice into their daily routine.

In order to increase improvement in word-finding:

- Encourage PWA to focus on practising the exercises requiring confrontation naming (particularly the naming of words in functional sentences exercise).
- Have a thorough rationale for tailoring the therapy exercises to the individual PWA.

7.9 INTERVENTION REFINEMENT

Interventions are subject to change, particularly technological interventions. The StepByStep approach has evolved over the last two decades (see chapter one, page 29). My doctoral research will contribute to further refinement of the intervention. Study two provided a comprehensive visual map of the intervention and a detailed written description of the intervention from multiple perspectives. Study four identified factors associated with the PWA carrying out more independent practice. Study five identified components of the intervention associated with improved word-finding. This information could contribute to an update to the StepByStep approach therapy manual including additional detail about the key components of the therapy, additional guidance for SLTs and volunteers/assistants about how to encourage more regular independent practice and encouraging SLTs to concentrate on delivering those aspects of the intervention most likely to result in improved word-finding. It is also worth considering the findings of the process evaluation in light of the component analysis. For example the 'using writing to cue naming' exercises were much practised, but were not associated with improved word finding so clinicians might want to consider hiding that step, if the PWA wants to concentrate on improving their word-finding. Furthermore, updates have already been made to the StepByStep software itself in order to restrict users from spending too much time on the 'using writing to cue naming' (i.e. spelling) exercise and moving them on to exercises with more confrontation naming elements, following these results. In addition, voice recognition improvements have been made to improve feedback and reduce frustration and technical difficulties.

Whilst the StepByStep approach to aphasia computer therapy was found to improve participants' word-finding in the Big CACTUS trial, the overall aim of improving word-finding was for PWA to be able to use those words in functional communication. However, no difference was found on the Therapy Outcome Measure Scale (TOMS; Enderby et al, 1997) between the computer therapy, usual care and attention-control groups (Palmer et al, 2019). Whilst there are some questions around the sensitivity of the TOMS to detect small changes (John et al, 2011), it is also possible that a component of the intervention relevant to generalisation was not delivered as intended. Multiple key informants in study two identified the importance of the role of the supporter in encouraging the PWA to use the words from the computer therapy in everyday conversation. It was suggested that this should be achieved through having conversations with the PWA, encouraging relatives and carers to do so and through playing word games (Palmer, 2015). The description of this aspect of the intervention was only one sentence in the therapy manual so may not have been seen as a priority to therapists when training the volunteers/assistants. Furthermore, it was only one sentence in the volunteer/assistant handbook (Palmer, 2015; appendix A). The process

evaluation subsequently established that volunteers/assistants spent a relatively small amount of time encouraging the use of words in conversation (median=45 minutes), considering the amount of input overall from the volunteer/assistant (median=4 hours, 15 minutes) and the amount of time spent using the computer therapy overall (median=26 hours). Therefore, I would recommend providing additional detail around what this aspect of the intervention should involve both in the therapy manual and the volunteer/assistant handbook so the importance of providing this component of the intervention is understood along with how to implement this component (additional description of related future research on page 257).

7.10 STRENGTHS AND LIMITATIONS

Strengths and limitations specific to each study have already been described in the discussion following each individual chapter. Therefore, the strengths and limitations described here are factors that impacted the study at a wider level.

This was the first in-depth process evaluation exploring the delivery of self-managed aphasia computer therapy. The lack of clarity or an accepted precedent regarding what is judged to be high fidelity, found in many of the studies included in the literature review (chapter two), demonstrated to the author the importance of having a clear process for scoring the degree of fidelity that was standardised across components of the intervention and elements of fidelity in the process evaluation. The additional detail about the delivery of the StepByStep intervention in the Big CACTUS trial has the potential to aid replication by SLTs delivering the intervention in clinical practice. One problem with replicating intervention delivery in clinical practice is having a sufficiently detailed description of how it was delivered in a research context. Another issue with replication can occur when clinicians adapt interventions to local context. This process of adaptation during the implementation process can have both positive and negative implications. Provided the key components of an intervention remain sufficiently similar to those trialled, minor adaptations to enable local delivery can increase use of the intervention without impacting on the desired outcome (Carroll et al, 2007; Chambers & Norton, 2016). Study five established components of the intervention that are 'essential' to improve word-finding. This information could help clinicians to understand which components of the intervention are most important to be delivered with high fidelity in order to ensure the desired outcome is still produced. It was only because the process evaluation measured each component separately, rather than creating a fidelity checklist with one overall composite score, that the component analysis could be carried out. Fidelity checklists cannot take into account the different weight/importance assigned to

different components (Abry et al, 2015). The component analysis was in itself a strength of this study as it helped to understand the mechanisms of action of the intervention.

The research described in this thesis only focused on fidelity to the computer therapy group in the Big CACTUS trial. Fidelity to usual care and attention control are described elsewhere (Palmer et al, 2019; Palmer et al; in press). Sixty one percent of attention control participants received the minimum recommended number of four puzzle books and four phone calls. Similar amounts of usual care were received across all three groups (Palmer et al, in press). The limited evaluation of fidelity to the attention control group compared to the intervention group means that treatment differentiation was not established (Moncher & Prinz, 1991). This aspect of fidelity is not included in the CFIF due to its origins in implementation research (Carroll et al, 2007).

The funding obtained for this doctoral research was awarded ten months after the trial had started to be set up. The author was involved in the trial from the outset as they worked on the trial as a research assistant. The limitation of the doctoral research commencing following trial set-up was that the identification of important intervention components to measure was carried out (i.e. study two was conducted) after recruitment had started. Furthermore, the ethics amendment to collect information for the fidelity evaluation was granted several months after participants had started to be recruited resulting in some of the data only being collected for some participants. These timing issues are specific to this thesis, but feed into a more widely applicable debate around whether one should establish the key components of the intervention and their mechanisms of action (through research rather than stating theory, which is commonly viewed as good practice; see MRC guidance on complex interventions; Craig et al, 2008) prior to evaluating the effectiveness of the intervention, or vice versa.

When evaluating the fidelity of a complex intervention it is never going to be possible to measure everything. In designing the fidelity evaluation of the StepByStep approach the author decided that the most rigorous method of choosing which components of the intervention to measure was to seek the views of StepByStep approach experts. Whilst this was a more rigorous consensus-based approach to identifying key intervention components, compared to the author making this decision alone on the basis of the written information available about the intervention, it did reduce the agency of the author. Having now developed expertise in the intervention over the course of carrying out the research there are other analyses of the data I would have liked to have explored, such as the impact of volunteer/assistant time spent encouraging the use of words in conversation on the TOMS score. In addition, lack of involvement of two of the key informants in the ranking exercise to

determine which of the components should be measured might have influenced which measures were selected, particularly as these two participants highlighted the importance of volunteers/assistants encouraging the use of words from the computer in everyday conversation.

In retrospect, I think it would have been valuable to have specified a theory of change based on the findings of the interviews with key informants, as recommended by Nelson et al (2012). A theory of change describes the anticipated mechanisms of action by specifying the components of the intervention and how these components are hypothesised to bring about the desired outcomes. The initial interview study results failed to make explicit the connection between how the different components were expected to result in the desired outcomes. The reason for the absence of this was the difficulty in combining the different opinions of the key informants. In a future project, the author would consider using a focus group or Delphi methodology to establish consensus and enable a theory of change to be developed.

Validated fidelity measures are available for few interventions. The lack of validity of the proxy measures used in the process evaluation (which also informed the secondary data analysis in study four and five) were a significant limitation of this research. The mismatch in the timing of the PhD and trial funding also impacted upon the amount of time available to develop more direct measures of how easy it was to use the software, how motivated participants were, the extent to which the vocabulary was thought to be personalised and the skill of the therapist delivering the intervention. The questions relating to personalisation, motivation and ease of use needed to be answered directly by the PWA as they are subjective opinions. Validated scales of motivation and usability are too complex to be accessible to PWA. Involvement of the Big CACTUS trial Patient and Carer Advisory Group in the development of the scales was a strength. However, eliciting written information from PWA is challenging and had more resources have been available it would have been preferable for the PWA to have completed them with face-to-face support from the therapist to aid their understanding of the questions. In terms of the measure of tailoring, it would have been preferable to have used the score given by the SLT with expertise in tailoring StepByStep on how logical the tailoring described was to judge the quality of the tailoring decisions, rather than how comprehensively the documentation had been completed. It is possible that the component analysis would have had a different outcome had the expert SLT had capacity to score all of the therapy planning forms for sense. The lead therapist quiz was designed as a measure of therapist skill, but on reflection the quiz was more likely evaluating therapist knowledge (see discussion page 237), which might be less likely to be associated with outcome.

There was no exploration of the fidelity of implementation from the perspective of SLTs delivering the intervention in this study. Interviews with healthcare professionals are often used to provide context about how an intervention was delivered across multiple different study sites, each of which is likely to have different social, organisational and political influences (Masterson-Algar et al, 2014). This angle was, however, explored by a master's student who identified SLTs issues working with the IT department, found that tailoring software helps to meet different patient/service needs but requires SLT time up front and found that therapists perceived assistants/volunteers are key to supporting and facilitating aphasia computer therapy (Burke et al, in preparation).

7.11 FUTURE RESEARCH

One of the most urgent avenues for future research is to explore ways to enable improved word-finding to be generalised to functional communication to inform important refinements of the intervention. The component of the intervention that key informants in study two perceived to be most important for generalising improvement into everyday conversation was volunteers/assistants encouraging PWA to use the words in daily life through conversation and word games. Data from the process evaluation indicated a paucity of volunteer/assistant time spent encouraging use of words in daily life. No information was collected about what this 'encouragement' comprised and little detail was provided in the therapy manual or volunteer/assistant handbook (Palmer, 2015). Further analysis of existing data could explore whether the amount of time spent encouraging use of words in conversation was associated with improved functional communication using the TOMS and/or the secondary outcome of the 'count of treated words used in conversation'. If this analysis demonstrates an association between time spent encouraging use of words in daily life and improved functional communication then it suggests that delivery of the existing component of the intervention needs to be improved. In that case, as well as recommending more time should be spent delivering this component, strategies to strengthen this aspect of the intervention could be developed using the Behaviour Change Wheel to guide intervention refinement (Michie et al, 2011). The three behaviour change techniques I would propose focusing on are: 1) more *training* for SLTs and volunteers/assistants around this component of the intervention, 2) *enablement* via the volunteer/assistant working with family/friends to create more opportunities for the PWA to use the words they are learning and 3) *modelling* use of words in practice scenarios with the volunteer/assistant (e.g. ordering food at restaurant).

However, achieving generalisation of gains made in therapy is known to be challenging. If no association is found between the amount of time spent encouraging use of words in daily life and functional communication outcomes, this indicates that the answer to achieving this may be more complex than improving the delivery of the existing component. Further work would then be required to identify strategies from the literature that may have assisted with generalisation in other neuro-rehabilitation interventions. It will be important to re-review underpinning theories such as learning theories and neuroplasticity theory in conjunction with identification of strategies that have worked in other areas of rehabilitation in order to propose and test possible additional components to the StepByStep approach required to lead to generalisation of word-finding improvement to everyday contexts.

From a methodological perspective, fidelity evaluations will always need to be tailored to the intervention in question. If future research explores the effectiveness of a refined version of the StepByStep approach, fidelity measures used in this research would benefit from further testing to establish validity. However, more generally researchers evaluating intervention fidelity would benefit from a comprehensive guidance document to enable researchers to understand the choices that need to be made in order to design a fidelity evaluation without having to search the fidelity literature more widely. For example, a guidance document could describe the various fidelity frameworks, explore the pros and cons of different methods of measurement (effectiveness versus efficiency) and the research contexts in which evaluation or enhancement are most appropriate.

7.12 CONCLUSIONS

This series of studies evaluated the intervention fidelity of the StepByStep approach to aphasia computer therapy. The intervention was found to have been delivered with moderate to high fidelity in the Big CACTUS trial. The insights from exploring adherence to aphasia computer therapy have the potential to influence how the intervention is delivered in clinical practice by encouraging therapists to think through who might best be able to adhere to computer therapy and how to enable those offered computer therapy the support to be able to carry out as much independent practice as possible. The findings also highlighted components of the intervention associated with improved word-finding, including rigorous tailoring of the computer therapy exercises by SLTs and PWA spending more time practising the 'using words in functional sentences' exercises. By sharing these findings with therapists, it might encourage them to deliver these components of the StepByStep approach with high fidelity, thus increasing the likelihood that the intervention will result in improved word-finding ability for PWA when implemented in clinical practice.

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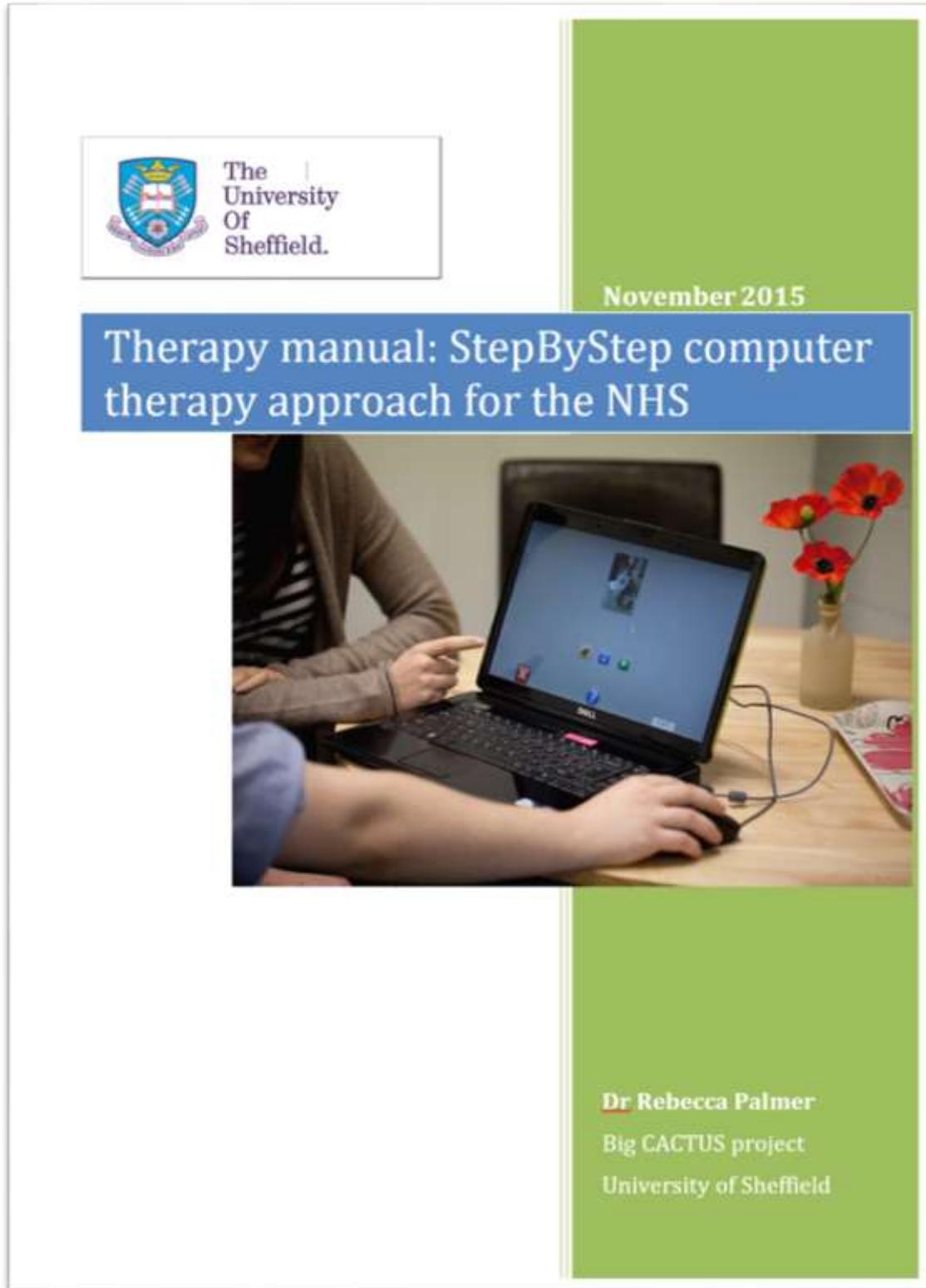
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Appendices

APPENDIX A: STEPBYSTEP APPROACH THERAPY MANUAL



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Appendix A - Volunteer/Assistant Handbook

Appendix B - User Guide for StepByStep v5

Background to the StepByStep approach to long term aphasia therapy

Speech and language therapy (SLT) is often received regularly in the first few weeks and months after stroke. Medical instability, fatigue and confusion may reduce full engagement with language therapy in the early weeks post stroke, reducing the opportunity for people to participate in treatment. There is evidence that people can continue to improve their language skills for several years [1] and The National Stroke Strategy (2007) [2] recommends people receive rehabilitation for as long as they benefit from it. Treatment of aphasia that persists beyond the first few months post stroke is often not available through NHS services in the UK as ongoing therapy is costly through face-to-face SLT and places greater demands on limited resources. To provide opportunities for people with aphasia to achieve their recovery potential, it is therefore necessary to provide efficient, affordable treatment options.

Targeted therapies with good preliminary evidence to date

Constraint Induced Aphasia Therapy (CIAT), also known as Intensive Language Action Therapy (ILAT), is based on the principle 'use it or lose it' from the observation that use of a skill encourages **neuroplastic** changes in the brain post injury, and avoids learned non-use. The CIAT makes use of language in games to make, reject or clarify requests for targeted items for 30 hours over 2 weeks [3, 4, 5]. A systematic review of 10 studies conducted over the decade concluded that evidence for this technique is favourable [6].

Model Oriented Aphasia Therapy (MOAT), which tailors treatment according to a patient's individual symptoms, was found to be comparable to CIAT when delivered with similar intensity [7]. Raymer et al (2008) found personal relevance or 'salience' of the language material being practiced to be important when targeting therapy [8].

While the optimum intensity remains unclear, it is generally acknowledged that for stroke rehabilitation regular, repetitive therapy practice is a factor in treatment success.

The resources required to achieve intensive therapy in the long term is prohibitive in the current financial climate and lower cost options for the support of repetitive, intensive practice are needed. **Non speech** and language therapy professionals have been employed successfully to support therapy activity [9, 10, 11]. Computer therapy, developed for the treatment of aphasia, has also been reported to be useful in the provision of targeted language practice and provides opportunities for independent home practice as part of a self-management approach to maximise practice intensity, improving outcomes for reading, spelling and expressive language [11, 12, 13, 14, 15]. The Department of Health report, 'Our Health, Our Care, Our Say' (2006) recommends self-management for **long term** conditions supported through technological innovation [16].

The StepByStep[®] computerised approach to long term aphasia therapy

The StepByStep computerised approach to long term aphasia therapy combines current evidence underpinning language therapy with practical considerations of treatment delivery. Skills of a qualified speech and language therapist are used to select individually targeted therapy exercises, computer software is provided for regular self-managed practice of therapy exercises, and volunteers or therapy assistant support language practice and computer use [17]. To encourage motivation for self-managed practice and reduce the likelihood of negative feedback leading to non-use of language, the StepByStep programme is designed using an errorless learning approach, whereby the patient begins to use exercises in which they experience some success before moving on to a harder exercise once the first exercise becomes easily achievable.

Key principles underpinning the StepByStep approach:

- Focus on using expressive language
- Tailoring exercises according to the patients symptoms

- Providing salient language practice material
- Intensity/regular practice of exercises
- Errorless learning (success with each exercise before progressing to a harder one)

Mode of delivery:

- Self-managed therapy practice using computer software (StepByStep v5)
- Support from non-speech and language therapy professionals

Preliminary evidence for this approach:

A pilot study evaluating this approach was carried out with 34 people with persistent aphasia. They were randomly assigned to the StepByStep approach, or usual long term care (most frequently this was social support). On average people with aphasia practiced their speech exercises on the computer independently for 25 hours over 5 months. The therapy showed statistically significant improvement in the ability to use spoken words when compared to usual care ($P=0.014$). The results indicated that self-managed computer therapy supported by volunteers (total of 4 hours on average) could help people with aphasia to continue to practise, improving their vocabulary and confidence talking [11]. Patients and carers found it an acceptable alternative to face-to-face therapy [18]. Self-managed computer therapy could therefore improve the quality of life of people with persistent aphasia, at relatively low cost and exploratory economic analysis has suggested considerable potential for the intervention to prove cost-effective [11, 19].

Summary of self-managed computerised therapy intervention

The StepByStep therapy approach targets word retrieval as it is one of the challenges most frequently experienced by people with aphasia, restricting their communication. The intervention was designed by speech and language therapists specialising in aphasia intervention and use of computer software for treatment. The StepByStep approach has been used for several years in independent practice and has been adapted in this manual for use within the NHS based on learning from the pilot study and from implementing the intervention into one NHS trust.

Key components

The three key components of the intervention were designed to incorporate key factors that research suggests positively influence aphasia therapy outcomes combined with practical considerations:

1. Qualified SLT assessment of patient's language profile to tailor computer exercises using the StepByStep© software so that they target the specific language deficit identified. Creation of exercises using target words of personal relevance to the patient.
2. Daily independent word finding practice with the tailored computer exercises by the patient over a 6 month period.
3. Volunteer/therapy assistant support to enhance adherence to the computer exercises and to encourage transfer of new words into functional daily situations.

Qualified speech and language therapist assessment and tailoring of exercises

A speech and language therapist should tailor computer exercises to the individual using 100 words of personal relevance chosen by the patient. There is a large bank of photographs within the computer software and if something extra is required (e.g. picture of a family pet, grandchild or favourite football team) it can easily be photographed digitally and added by the SLT.

The computer software enables the SLT to select exercises using these words that follow steps in the therapy process that the therapist would take if delivering it face-to-face. The SLTs delivering this intervention should receive training on how to set up appropriate exercise steps. The SLTs should base the selection of exercises on language skills demonstrated in initial language assessments. The steps can then be applied to all sets of vocabulary.

The SLT should provide initial face-to-face demonstration of the software exercises and spend up to 2 hours (spread over 1-3 sessions) checking that the individual is able to use the software and monitoring the appropriateness of the tailored exercises. The SLT should also review the need for additional pieces of hardware such as tracker balls in order to make it physically possible for patients to use the computer.

If a speech and language therapy department has access to the StepByStep telehealth module, therapists or therapy assistants could use this as a source of monitoring progress and updating exercises. Therapists should limit this method of monitoring to once every two weeks.

Regular self-managed practice

The patient should be asked to work through the exercises on the computer aiming to practice each day for 20-30 minutes. Patients should be given a 6 month period to work through the therapy material on the computer and practice using the new vocabulary in their daily lives. Due to holidays and bouts of illness during a six month period of time, breaks from using the software should not be unexpected but regular use over at

least four of the six months should be encouraged. The amount of practice will be captured automatically by the computer programme.

The software is designed for life long use should the patient wish. The initial six months of tailoring by a speech and language therapist and support from a volunteer/ assistant is intended to assist with learning to self-manage. In the Big CACTUS study those patients who have the software installed on their own computers will not be prevented from continuing to practice if they wish following the 6 month supported intervention time. If computers were loaned, they may be taken back after 6 months to give to a new patient (as permanent loan of equipment would be unusual in practice).

Volunteer/assistant support to assist with treatment adherence and carry over into daily activity

To enhance treatment compliance, the SLT should provide training to local volunteers who already have a working relationship with the SLT department (based in NHS trusts, local voluntary organisations, or student SLTs) or therapy assistants based in the department. They should use the training programme and volunteer/assistant handbook developed and evaluated during the CACTUS pilot study. The volunteer/assistant should follow the instructions set out in the handbook (see Appendix A).

The volunteer/assistant should be asked to visit the patient once a month for an hour, or every two weeks for half an hour (to suit the patient). It may be that more frequent visits are required initially, followed by less frequent visits as the patient becomes better able to use the software.

The volunteer/assistant should carry out the following tasks:

- provide technical assistance
- observe and encourage use of computer exercises
- check results and discuss difficulties
- assist patient to move on to harder tasks in the therapy process pre-programmed by the SLT
- encourage the use of new words in everyday situations through word games, conversation and discussions with family about how to encourage use
- set up new vocabulary sets if all 100 words have been completed

The patients should be able to contact the volunteer/assistant by telephone for technical advice on computer use between planned visits if necessary.

The volunteer/assistant should complete a feedback form after each visit and send it to the SLT. The SLT should use this to monitor the volunteer/assistant support and the progress of the patient and provide guidance to the volunteer/assistant on how to proceed. Volunteers/assistants may be invited to meet together with their peers and the SLT for an hour every few months for support and discussion of issues arising and new practice material required by their patient. The volunteer/assistant may contact the SLT by e-mail, telephone or face to face between support sessions to report any concerns/difficulties.

Resources required for the intervention:

Speech and language therapist

The speech and language therapist providing this intervention should hold a speech and language therapy qualification from an institution recognised by the Royal College of Speech and Language Therapists. The therapist should have experience of providing therapy to people with aphasia as a consequence of stroke. They should have received training on how to use the software and provide the StepByStep intervention.

Therapy assistant / volunteer

A therapy assistant should work for the same NHS trust as the therapist and be part of the team supporting speech and language therapy interventions. The assistant may be a specific speech and language therapy assistant or a more generic rehabilitation/therapy assistant.

A volunteer should hold appropriate DBS checks from the NHS trust from which they are supporting patients or from local voluntary organisations with existing relationships with the speech and language therapy department.

All assistants and volunteers should undergo the same training to support the intervention as provided in this manual.

Support should not be provided by any staff or volunteers who have not undergone the training provided in this manual. Additional informal support may be provided by a relative or carer however.

Software

This intervention uses the StepByStep v5.0 software from Steps Consulting Ltd [20].

Hardware

The software should be installed on either the patient's home computer if they have one, or on an NHS computer available to loan for a six month period.

StepByStep v5 works on Windows 7 and Windows 8 on a laptop, desk top or tablet. It does not work on Windows XP, a Mac or on an iPad at the time of writing this manual.

The computer should have good speakers from which the words spoken can be heard clearly. For recording purposes, the computer either needs to have a good internal microphone, or, if recordings from this are quiet or distorted, an external microphone should be provided.

Screen size and resolution should be considered so that the pictures and words are large enough for the individual patient to see clearly.

Some patients may require tracker balls or external mice in order to gain physical access to the computer.

Assessment of the patient's language, tailoring of the computer software and provision of support (Speech and language therapist role)

Assessment of the word finding deficit

As a minimum, patients should have their naming ability assessed with a standardised naming test. In the Big CACTUS project, the Naming objects test in the Comprehensive Aphasia Therapy test (CAT) should be used. The results of this assessment should guide the clinician to understand the severity of the word finding deficit and the types of error made e.g.

- semantic paraphasias (chair → table)
- phonemic paraphasias (brollie → broccoli)
- literal paraphasias (umbrella → umblerefa)
- neologisms (chair → wibble)
- perseveration (saying a previous word again)

The performance on the assessment along with observation through conversation should indicate the types of cue which best assist the patient to find the correct words e.g.

- a phonemic cue ('tel'... → television)
- a semantic cue ('you wear this on your head' → hat, 'it's an animal you might have as a pet' → cat)
- a written cue (first letter or whole word, provided by the therapist, or written on paper/sky writing by the patient)
- visual cues (can the patient copy the word from hearing it, or do they need to see your lips?)
- how aware is the patient of his/her errors on assessment? Do they need to be encouraged to listen to their own production?

Assessment of the patient's interests and areas of their life where increased vocabulary may improve participation.

The therapist should discuss what vocabulary would be meaningful for the patient to learn. This can be conducted with the patient and with input from friends and relatives. Pictures can be used to assist patients in indicating topics that are of importance to them. Once the patient has been added in the clinician version of the StepByStep programme, the therapist should show the pictures/words available within each of the topics the patient indicated are of importance. Further topics and words should be added as necessary to make the therapy material as personalised as the individual requires. For example,

- If a patient wishes to learn family names, the therapist should input photos of family members
- If a patient doesn't recognise the picture on StepByStep the therapist should change it for a picture more familiar to the patient, using either google images, or photographs of the patient's own version, the patient's own cat for example.
- If a patient uses a different but acceptable word for an object, the therapist should change this within the StepByStep programme to reflect the patient's variant of that word (this might be a regional variation)

In the Big CACTUS study 100 words should be selected for practice over the following six months. Vocabulary sets should be grouped according to topic.

Refer to the Big CACTUS training slides, or the StepByStep website for instructions on how to select personalised vocabulary sets.

Tailoring the computer therapy exercises

The therapist should set up therapy steps to assist the patient learn their chosen vocabulary. There are seven steps that will automatically be applied to each set of vocabulary.

Picture recognition

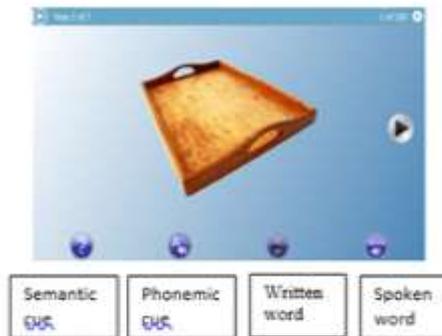
This step is designed for familiarisation of the vocabulary by using simple matching tasks.

As standard, this step is set up as a written word to picture match from a choice of two pictures (A). In Big CACTUS we request that therapists change this standard step to show the picture for the patient to match with the picture and written word below, so they focus on the picture that will be presented in later steps, and hear the target word spoken and see it written (B)



Confrontation naming

This step provides the patient with a target word with cues at the bottom of the screen. The patient should be encouraged to click on the clues from left to right to help prompt retrieval of the word.



Confrontation naming with feedback

The exercise in this step is designed to encourage the patient to name the word with feedback on whether the correct word has been retrieved. If the patient needs a clue, the written word can be presented on pressing the dictionary icon. If the microphone button is pressed, once the patient records the spoken word, speech recognition is used to determine whether it is the correct word.



Using writing to cue naming

This step shows an anagram for the patient to unscramble and name the word. Once the patient knows what the word is he/she can press the microphone button, record the spoken word and receive feedback.



Naming from a grid

This step requires the patient to name pictures without cues. The patient should be instructed to press the microphone button to record the spoken word. The computer will indicate whether the word was correct.



Eight pictures are shown in the grid as standard. This should be changed if this is too many for the patient. See Big CACTUS training slides or StepByStep website for instructions on how to change this presentation.

Naming from memory

This step requires the patient to remember what was in the grid in the previous step. They should be instructed to click on the microphone icon and say a word they can remember. If they produced one of the words, the picture will be revealed. If they need a reminder the patient can choose to flash all of the pictures up with the microphone? button. This step is linked to the previous step, so if eight pictures are too many for the patient to remember, changes should be made to the previous step.



Using words in functional sentences

This step asks a question and requires that the patient answers the question using the target word in a sentence.



There are two sentence steps to provide the patient with practice using the target words in different sentences

Therapy steps should be tailored according to the needs of the individual patient. The therapist should consider two issues when tailoring:

- 1) The steps should be of incremental difficulty to enable progression to achieve unaided word retrieval through an errorless learning approach.**

If one type of step is particularly difficult for the patient, the therapist should copy the step and tailor it to make it more achievable before the patient tries the original step.

Example 1:

If presentation of lots of cues on the same page is confusing for the patient, the confrontation naming task should be copied and adapted to show different cues in different steps.

Example 2:

If unravelling an anagram is too difficult, this step should be copied and adapted to enable the patient to practice copying the word with the letters presented in the correct order before moving on to try the anagrams again.

This intervention is designed to improve word finding using the principles of 'language action' therapy. Practising production of words should be the target of the majority of therapy exercise steps set up.

- 2) The steps should present cues that are most likely to be useful as informed by the naming assessment and conversation with the patient.**

Definitions of prompts available		
		This is a semantic prompt providing a video of someone describing the meaning of the word.
		Click here to see a video showing the mouth movements when saying the whole word.
		Click here to see a video giving the first sound of the word.
		Click on the dictionary button to display the written word for the picture.
		Click here to see the first letter of the word in the picture.
		Click once to see the sentence shown on the screen. Click again to hear the sentence spoken.
		Click here to record your attempt and hear it played back.
		Voice recognition - say the word and the computer provides feedback of accuracy.

Example 1:

Use semantic cues on confrontation exercises if semantic prompts helped the patient to find the words during the naming assessment.

Example 2:

If on assessment the patient was able to repeat words, but only when watching your lips, provide a whole word repetition cue with a video. As a second step or second cue, provide the sound cue with a video.

Example 3:

If the patient is able to repeat words easily and phonemic cues helped word retrieval on assessment, the therapist should provide phonemic cues in the confrontation naming exercise, followed by the whole spoken word cue in case it is needed. If phonemic cues help the patient on assessment without the need to look at lips, there is no need to record videos to accompany these sound prompts.

Example 4:

If patients appear unaware of their errors on assessment, recording and playback button can be added to the exercises to promote self-monitoring of word production.

Example 5:

Some patients cue themselves in with written word, first letter, or sky writing. If the patient uses this strategy during assessment, or if their writing is better than their spoken language, the therapist should provide a written letter cue, followed by a whole written word cue if the written letter cue doesn't always work.

Patients will require different sets of cues depending on what is shown to assist them during the formal assessment and informal conversation.

Although StepByStep provides a range of cues for each word in the library, the therapist should check that the cues needed for the patient are present for each chosen word in the vocabulary sets. Therapists should add any missing cues that are indicated from the assessment. (There is no need to record spoken sound, words and sentences, written letters, words and sentences, semantic or sound videos for all vocabulary items if not required by the patient).

If additional cues need to be recorded, the therapist should ensure that the recordings are clearly audible and/or visible.

Cues should be ordered from minimum to maximum assistance from left to right.

The exercise configuration should be applied in the same way to all of the vocabulary sets.

Please see Big CACTUS training slides or StepByStep website for details of how to record cues, and how to modify the exercise steps.

Training the patient to use the StepByStep programme

Once the therapy programme has been tailored for the patient, the therapist should show them how to use the exercises.

The therapist should show the patient the following

- How to switch on the computer and open the StepByStep programme
- The calendar and how this shows how much practice has been carried out
- How to select the vocabulary they want to practice
- How to carry out each of the steps (one or two examples from each step can be shown)
- How to move up to a harder task if the current one feels too easy.

The therapist should leave the patient (and carer if available) with the user guide/instruction booklet (see appendix A) which provides reminders of how to use the programme and what is required for each type of step. The therapist should annotate the instruction book with any additional instructions.

The booklet recommends that the patient tries to practice for 20-30 minutes each day. The therapist should discuss this with the patient and help to identify times of day when the patient can fit practice into their daily routine.

The therapist should leave their contact details and arrange a further visit to introduce the volunteer/assistant if not present at the training visit. If a further visit is made to introduce the volunteer/assistant, the therapist can check the appropriateness of the tailored steps, make alterations if necessary, and sort out any initial difficulties the patient has experienced since the previous visit.

Training and support of volunteers

The therapist should deliver training to volunteers and/or assistants either as a group or on a one-to-one basis. The therapist should take the volunteer/assistant through the volunteer/assistant handbook and familiarise them with their responsibilities and how to carry them out (see appendix A for handbook).

When a patient has been identified for the volunteer/assistant to support, the therapist should meet with them to explain the way the patient communicates and provide advice on any specific communication strategies required for the individual patient before their first visit (a brief meeting immediately prior to the visit or a discussion in the car on the way to the visit is often most practical). The therapist should accompany the volunteer/assistant on their first visit to introduce them to the patient. The therapist should go through the patient's tailored exercises on the computer and refer them to the user guide given to the patient (see appendix B). The volunteer/assistant may accompany the therapist to familiarise themselves with the individual patient's exercises and support required either at the time the therapist provides the exercises to the patient, or at a further visit 1-2 weeks later. Before leaving the patient's house the therapist should ensure the patient and volunteer/assistant exchange best contact details. Following the visit, the therapist should provide a short debrief (often in the car, or outside the patient's home) to summarise what they need to assist this particular patient to try and achieve and to check that the volunteer/assistant feels comfortable and confident to visit independently on future occasions. The therapist should remind the volunteer/assistant to contact them with feedback forms after their next visit.

The therapist should ensure that the volunteer/assistant has copies of the feedback form (see volunteer/assistant handbook and printable copy of the form in appendix A) and ensure they know that they must return a completed copy to the therapist after each patient visit.

The therapist should review the feedback forms and respond to the volunteer/assistant by phone, e-mail or in person for support and recommendations. Changes to the exercise set up and additional vocabulary can be made by the volunteer/assistant under the guidance of the therapist.

If there is more than one volunteer/assistant performing the support role, peer support meeting can be arranged with everyone by the therapist as a chance to discuss ideas and issues occurring.

Volunteer/assistant role

The volunteers/assistants should refer to their handbook for supporting the intervention. Please see appendix A.

Amendment 1 (18th May 2015)

StepByStep computer therapy – tips

Selecting cues

StepbyStep gives you the option to record a range of cues that might help a patient to retrieve each of the words they have chosen to practise. You do not need to record all cue options for every word. Rather, you need to decide which cues are most likely to help your patient and make sure they have been recorded e.g.

Videos of single sounds or whole words (mouth movements)	Required if repetition of words is particularly difficult, but not required if patient can repeat words from an auditory example
Audio recording of single sounds	Required if sound cues help patient to retrieve the word (now all included in the latest update)
Audio recording of whole words	Required for repetition/hearing target words
Video/audio recordings of semantic cues	Only required if semantic information helps the patient to retrieve words.

If you need to record a lot of new audio/video material, consider whether your volunteer/assistant has the time and skills to help you with this. If unsure whether a particular cue will be helpful from initial assessment, but think that it could be, record the cue just for a subset of the 100 words initially. You could ask the volunteer/assistant to check how the patient responds to this cue in their feedback form. If it seems to be helpful, consider visiting to add it in for other words, or explaining how to add the cues in to the volunteer/assistant.

Selecting/changing steps

For many people, the existing steps may be appropriate. You may need to consider changing the existing steps to change the types of cues available e.g. hiding the semantic cue button if they are not of any help to the patient. Occasionally, you may wish to add in a step e.g. if more work on spelling is required and you think a greater range of spelling exercises would be beneficial.

Hide/Show words

Not all of the 100 words need to be displayed to the patient at once. If a patient is more severe and you think they would benefit from concentrating on 10 or 20 words to start with, consider hiding the others, and making sure the volunteer/assistant 'shows' more sets of words as the patient progresses with their therapy.

NB. If you are having difficulties ensuring your patients have regular visits from a competent volunteer/assistant, it may be better to leave all words available for practice so as not to disadvantage patients from continuing to practice more words.

Feedback

Where remote access to the patient's computer exercises is not possible, feedback to and from the volunteer/assistant is important to enable you to know how the patient is doing and to recommend any adjustments to the exercises being practised or to the cues used, and also for making suggestions regarding ways to practise the new words in everyday settings, away from the computer.

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APPENDIX B: BIG CACTUS TRIAL PROTOCOL

 <p>The University Of Sheffield.</p>	<h1>Big CACTUS</h1>
	<p>A study to assess the clinical and cost effectiveness of aphasia computer treatment versus usual stimulation or attention control long term post stroke (CACTUS)</p>
	<p>RESEARCH PROTOCOL (Version 5.0) 31 May 2017 Sponsor R/134248 Funder HTA 12/21/01 RECS Leeds West 13-YH-0377 Scottish A REC 14-SS-0023 ISRCTN 68798818 Authorised by: Dr Rebecca Palmer</p>

Sheffield Clinical Trials Research Unit (CTRU)

A study to assess the clinical and cost effectiveness of aphasia computer treatment versus usual stimulation or attention control long term post stroke (CACTUS)

This document describes a clinical trial, and provides information about procedures for entering participants. The protocol is not intended for use as a guide to the treatment of other patients. Amendments may be necessary; these will be circulated to known participants in the trial.

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Abbreviations

AE	Adverse event
Carer QoL	Carer Quality of Life measure
CAT	Comprehensive Aphasia Test
CI	Chief Investigator
CLRN	Comprehensive Local Research Network
CONSORT	Consolidated standards of reporting trials
COAST	Communication Outcomes After Stroke
CRF	Case report form
CTRU	Clinical Trials Research Unit
DMEC	Data Monitoring and Ethics Committee
EQ5D	European Quality of Life measure (5 Dimensions)
GCP	Good Clinical Practice
HRQoL	Health related quality of life
ICER	Incremental cost effectiveness ratio
ICF	International Classification of Functioning, Disability and Health
IMP	Investigational Medicinal Product
HTA	Health Technology Assessment
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NHS	National Health Service
PI	Principle Investigator
QALY	Quality adjusted life year
R&D	Research and Development
RCT	Randomised control trial
REC	Research ethics committee
SAE	Serious adverse event
SOP	Standard operating procedure
SHSC	Sheffield Health and Social Care (NHS Foundation Trust)
SLT	Speech and language therapist/therapy
TOMS	Therapy Outcome Measures
TMG	Trial management Group
TSC	Trial Steering Committee
VAS	Visual analogue scale

Definition of terms

Aphasia	A neurological language deficit affecting the ability to understand, talk, read and write
Stroke	An acute neurological event (infarct or haemorrhage) of sudden onset

General information

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Protocol amendments since Version 1.0

Protocol version 1.0, 30 October 2013 amended to version 2.0, 20 June 2014. Summary of main changes:

- I. Trial Summary, page 7 & page 20: One part of the primary outcome has been moved to the secondary outcome as agreed by both the Trial Management Group and Trial Steering Committee. One of the primary outcomes had two measures associated with it. To reduce complexity of analysis the primary outcome (conversation) will be measured by the Therapy Outcome Measures alone. The number of target words used in conversation will now be a secondary outcome.
- II. Duration (page 13) & Data recorded during the intervention period (page 20): Clarification that follow-ups should be carried out within one month of each time-point. This will reduce participant burden by ensuring that there is at least 2 months between outcome measure assessments at 6, 9 and 12 months.
- III. Participant Identification, page 14: A section has been added from the IRAS form to provide more information.
- IV. Planned inclusion and exclusion criteria, page 14: Clarification of wording - Exclusion criteria point 2 has been removed and re-worded as point 7 of the Inclusion Criteria. Points 5 and 6 of the Inclusion criteria have been clarified and scoring added.
- V. Change to number of target words from 96 to 100 (pages 17 & 18, and Appendix 2 & 4): The upgraded software no longer use sets of 12 words, so we are now using 100 words, instead of 96 (8 sets of 12).
- VI. Data recorded during intervention period, page 22 & Appendix 3: An additional 3 month phone call will be made by the PI to check on the participant's health and the usual care they are receiving.
- VII. Safety Assessments, pages 23 & 24: Additional information has been added about Adverse Events and Serious Adverse Events, including examples of events, and the reporting process.
- VIII. Flow charts in Appendix 2 3 & 4, pages 34-37, have been amended as above.

Protocol amendments since Version 2.0

Protocol version 2.0, 20 June 2014 amended to version 3.0, 12 February 2015. Summary of main changes:

- I. Pages 5 and 6: All confirmed NHS sites and Principal Investigator details have been added
- II. Duration, page 14: Further clarification has been given of when follow-ups should be made. The sentence "Follow-ups should be carried out within one month of each time-point" has been amended to "Follow-ups should be carried out in the month following each time-point" (e.g. 6-7 months, 9-10 months, 12-13 months)." This is to ensure that the follow-ups are carried out within six to seven months, for example, not before 6 months. The phrase 'within one month of each time-point' could be interpreted to mean a few weeks before the time-point.
- III. Regular self-managed practice, page 18: An additional 'Per protocol' definition for intervention use has been added for clarity - "across at least a four month period will be considered per protocol". The recommended amount of practice is 3 x 20 mins per week for 6 months (eg. approximate total of 24 hours). The practice must be spread over at least 4 of the 6 months, but it doesn't matter how much practice occurred in each of the months to be considered part of the per protocol analysis.
- IV. Table 1 'Summary of outcome measures', page 22: The ~~Carscop~~ measure had been omitted in error from the table; additional information has been added to the EQ5D section, listing the three different versions of the EQ5D to be used in the trial.
- V. Statistics, Section 9, page 25: The paragraph 'Assumptions for the sample size calculation' has been amended as the figures were documented the wrong way round for 'assessment of conversation' and 'patient rated improvement'.
- VI. Data Handling & record keeping, section 11, pages 29 and 30 - this has been amended to match the information provided on the original ethics form in IRAS, to clarify how patient identifiable information is transferred and stored securely on the web-based database.
- VII. Appendix 1 and 2, pages 34 and 35: added "age 18" as this had been omitted in error from the flow chart.
- VIII. Appendix 2, Flow diagram, page 35: added "with at least 50% accuracy (score of 5/10)" to the Eligibility criteria 'Ability to perform a simple matching task in StepByStep', to provide more detail of the scoring and to be consistent with the 'Planned inclusion and exclusion criteria' on page 14 of the protocol.
- IX. Appendix 2 Flow diagram, page 35: amended the 'informed consent' section to say 'forced alternative cards' instead of 'yes/no cards' as the wrong description of the cards to be used was written in error.

Protocol amendments since Version 3.0

Protocol version 3.0, 12 February 2015 amended to version 4.0, 17 July 2015. Summary of main changes:

- I. Trial treatment, section 7, pages 19-20: the description of the intervention arm was written prior to the trial starting, based on the pilot study, some minor adjustments to the intervention protocol were decided prior to the study starting and these are reflected in the changes made to this section. These include 1) using version 5 (rather than 4.5) of the StepByStep software, 2) using different documents to maintain and record fidelity of StepByStep setup, 3) using a feedback form for communication between SLT and volunteer/ therapy assistant and 4) not training volunteers or assistants to use word pair barrier games.
- II. Trial treatment, section 7, pages 21-22: a section has been added to detail how the intervention fidelity will be evaluated, this explains how existing measures will be used and additional measures will be collected. The additional measures include a quiz for lead therapists to explore drift in knowledge about the intervention over time, a measure of working alliance to be completed by the volunteers/therapy assistants and three additional questions to be added to the participant diary.

Protocol amendments since Version 4.0

Protocol version 4.0, 17 July 2015 amended to version 5.0, 31 May 2017. Summary of main changes:

- I. Page 4-6: Change in Principal Investigator details
- II. Page 6: Change in Service User member on Trial Steering Committee (previous member resigned due to ill-health)
- III. Page 12 and page 25: Clarification of measuring the picture naming task as not all participants were assessed on 100 words, a percentage rather than a number is required for analysis. Wording amended from "The change in the number of words" to "The change in word finding ability of words personally relevant to the participant will be measured by a picture naming task (100 words with a maximum of 2 points each). The word finding score will be expressed as a percentage of the total score and change in the percentage 6 months from baseline will be calculated."
- IV. Page 12: Clarification of the statistical analysis to reduce ambiguity about ~~its~~ interpretation amended from "Primary and key secondary outcomes will be analysed using a Hochberg testing procedure." to "Primary and key secondary outcomes will be analysed using a multiple linear regression model adjusted for baseline measures and stratification factors. Hochberg testing procedure will be used to control for multiplicity due to multiple treatment comparisons and three endpoints (co primary and key secondary)."
- V. Page 15: Clarification of objectives measured separately between participants and carers. Point 3 amended from "To investigate whether patients receiving self-managed, computerised speech and language therapy and their carers perceive greater changes in social participation in daily activities and quality of life (participation)." to exclude the
- VI. ~~wording~~ "and their carers".
- VII. Page 15: wording added to the subsequent paragraph "and the impact on the carer quality of life".

- VIII. Page 16: Clarification on the Consort diagram of the two distinct measures within the CarerCOAST by adding "CarerCOAST (last 5 items for carer)" (See changes to pages 26 and 27 below.)
- IX. Page 18: Point 5. Wording changed from "Ability to retrieve 10-90% of words" to "Ability to score 5-43 / 48 on the CAT Naming Objects sub-test [25] (Mild 31-43, Moderate 18-30, Severe 5-17)" as scores not percentages were used on the randomisation system.
- X. Pages 19 and 20: Further clarification of scores not percentages used for the CAT Naming Objects test: page 19 "If the word finding score is less than 5 (10%), or greater than 43 (90%);" page 20 "(Mild 31-43, Moderate 18-30, Severe 5-17)."
- XI. Page 25: Details have been added about the process followed for rating the videos in relation to one of the primary outcome measures, measures the change in functional communication using the activity scale of the Therapy Outcome Measures: "We will carry out a benchmarking session using the TOMS with potential raters to get consensus as to how the TOMS will be used in this project, followed by inter and intra rater reliability tests using 10 practice videos. Raters selected for final rating of all participant videos will have intra rater reliability of at least 70% practice videos rated within 0.5 between time 1 and time 2, and inter-rater reliability of at least 70% videos rated within 0.5 of the median scores at both time points. Refer to separate document 'Process for selection of TOMS raters and scoring procedure October 2016' for additional detail."
- XII. Pages 26 and 27, including table on page 27: Clarification of the CarerCOAST. The CarerCOAST assesses carer perception of patient's communication effectiveness, and impact of the patient's communication on the carer's quality of life. The measure has 20 items. The first 15 items assess carer perception of patient's communication while the last 5 items measure the patient's communication difficulties on the carer's quality of life. This distinction needs to be clarified in the protocol as they will be analysed separately. Wording amended to include "the last five items of the CarerCOAST."
- XIII. Pages 26 and 27: Clarification that carer will complete the EQ5D carer questionnaire by including the word 'carer'.
- XIV. Page 31: Clarification of the statistical analysis to reduce ambiguity about its interpretation: "Primary and key secondary endpoints for the comparisons of Control to Intervention and Active Control to Intervention will be analysed using a Hochberg testing procedure which allows for an investigation of all three endpoints whilst maintaining the overall Type I error at 5% [35]" amended to "Primary and key secondary endpoints will be analysed using a multiple linear regression model adjusted for baseline measures and stratification factors. Treatment comparisons (Intervention vs Usual Care and Intervention vs Attention Control) will be based on Hochberg testing procedure to allow for an investigation of all three endpoints (co primary and key secondary) whilst maintaining the overall Type I error at 5% [35]."
- XV. Pages 32 and 33: Clarification of the statistical analysis to avoid ambiguity of interpretation. Re-worded from: "The mean difference in percentage improvement of words named correctly between the treatment and control groups, adjusted for baseline naming ability, will be analysed using an analysis of covariance (ANCOVA). Terms for treatment and baseline will be fitted into the model. Assumptions underlying the analyses will be assessed by inspection of residual plots. Homogeneity of variance will be assessed by plotting the studentised residuals against the predicted values from the model, whilst Normality will be assessed by use of Normal probability plots. If the

assumptions for the analysis of variance are violated then appropriate transformations may be applied or alternative analyses may be performed. Similar analyses will be undertaken for the endpoints of COAST and the activity scale of the TOMS. The endpoints at 9 and 12 months will be similarly analysed for exploratory purposes. Likewise an investigation of trends over time will be made."

Re-worded to: "For the change in word finding (expressed as a percentage) at 6 months from baseline, the measure of intervention effect will be the mean difference in change in word finding ability between the Intervention and Usual Care groups, and the Intervention and Attention Control groups. A multiple linear regression model adjusted for baseline word finding ability and stratification factors (centre and severity of word finding) as fixed effects (39).

The outcome will be modelled as a function of:

- word finding ability at baseline,
- treatment group (Usual Care, Attention Control, Intervention),
- centre as a fixed effect and,
- the severity of word finding as a fixed effect (mild, moderate, and severe).

Results will be reported and presented as adjusted mean difference in word finding ability between the Intervention and Usual Care groups, and the intervention and Attention Control groups, and Attention Control and Usual Care (for exploratory), with its associated 95% CI and associated P-value.

Improvement in functional communication at 6 months assessed using activity domain of the TOMS, which is a ~~primary~~ endpoint will be analysed in the same manner as for the change in word finding ability but adjusted for baseline functional communication (rather than the change in word finding ability at baseline) in addition to stratification factors.

Likewise, the endpoints at 9 and 12 months and other continuous outcomes will be analysed using a similar approach for exploratory purposes."

XVI. Page 33: Details of the key subgroup analyses have been added:

"Analysis will be carried out on key subgroups:

1. Severity of word finding difficulty

Mild 31-43

Moderate 18-30

Severe 5-17

2. Length of time post-stroke

The research team will undertake a blinded review to determine the groups by plotting the primary outcomes against length of time post-stroke.

3. Baseline comprehension ability based on the CAT sentence comprehension scores

Within normal limits 27-32 (based on CAT cut off score for normal/aphasic)

Mild comprehension impairment 18-26

Moderate comprehension impairment 9-17

Severe comprehension impairment 0-8

(0-8 = inconsistently understanding at 2 Information Carrying Word (ICW) level; 9-17 = consistently understanding at 2-3 ICW level/simple sentence structures but not complex sentence structures; 18-26 = some understanding of complex sentence structures but not consistent.)"

Trial Summary

Big CACTUS is a pragmatic randomised controlled trial (RCT) to compare outcomes for people with persistent aphasia using computerised speech and language therapy (SLT) at home with those having usual care (standard speech and language therapy provision or general daily communication activity), or attention control (daily completion of puzzle book activities). The study uses a CE marked medical device as used for its intended purpose. The sample size is 285 patients (95 per arm). The estimated recruitment rate is one participant per month at each site. An internal pilot phase with a review of progression criteria half way through the recruitment phase is planned.

Setting

Computer therapy exercises will be provided in participants' own homes. Recruitment, assessment and tailoring computer exercises will be coordinated by 20 Speech and language therapy (SLT) departments across the UK, with a 15 month recruitment period at each site.

Target population

People presenting with word finding difficulties as part of their aphasia (language disorder affecting understanding, talking, reading and writing) at least 4 months post stroke with no upper limit.

Health technologies being assessed

Participants will be supported to self manage continued daily word finding exercises for using the StepByStep© computer software for 6 months. Computer exercises will be tailored to individual needs by a SLT, followed by volunteer or SLT assistant visits for support.

Measurement of costs and outcomes

All outcome measures will be made at baseline, 6, 9 and 12 months by blinded speech and language therapist assessors at each site.

Primary outcomes:

1. The change in word finding ability of words personally relevant to the participant will be measured by a picture naming task (100 words with a maximum of 2 points each). The word finding score will be expressed as a percentage of the total score and change in the percentage 6 months from baseline will be calculated.
2. Improvement in functional communication will be measured by blinded ratings of video recorded conversations between a SLT and participants, using the activity scale of the Therapy Outcome Measures.

Key secondary outcome:

Improvement in patient perception of communication will be measured using the COAST - a patient reported measure of communication participation and related quality of life. Use of learnt vocabulary in the context of conversation will be measured using a checklist of target words during rating of the videoed conversations at 6 months.

Cost effectiveness measurement

A cost-utility analysis will be undertaken from the NHS and personal social service perspective. Intervention and SLT time costs will be estimated for individuals. The EQSD (accessible and by proxy versions) will be administered at all time points and combined with standard valuation sources to measure quality adjusted life years (QALYs) gained in each group. EQSD and CarerQoL scores will also be elicited from carers. An economic model developed alongside the pilot study will be updated. Differences between costs and QALYs in the 3 groups will be described and the incremental cost effectiveness ratio (ICER) will be calculated.

Analysis

Primary and key secondary outcomes will be analysed using a multiple linear regression model adjusted for baseline measures and stratification factors. Hochberg testing procedure will be used to control for multiplicity due to multiple treatment comparisons and three endpoints (co primary and key secondary).

1. Introduction

Stroke is the largest cause of disability in the UK with communication impairment affecting one third of survivors. Speech and language therapy (SLT) is often received weekly initially but rarely continues after the first few months. Medical instability, fatigue and confusion may reduce full engagement with language therapy in the early weeks post stroke, reducing the opportunity for people to achieve their potential for recovery. The prevalence of speech and language disorders 6 months after stroke is therefore still considerable (50 per 100,000). There is evidence that people can continue to improve their language skills for several years, continuing to lessen the effects of aphasia. As the consequences of aphasia remain a problem long term, investigation of interventions to reduce this health burden in the chronic stages post stroke is crucial. The National Service Framework for Long term conditions (2007) and the National Stroke Strategy (2007) recommend people receive rehabilitation for as long as they benefit from it. Treatment of aphasia that persists beyond the first few months post stroke is often not available through NHS services as ongoing therapy is costly through face to face SLT and places greater demands on already limited resources.

Meta-analysis in a Cochrane review (2012) of speech and language therapy (SLT) for aphasia following stroke suggests some effectiveness, particularly if delivered intensively [1]. Adequately powered RCTs in this field are rare except for recent studies of SLT intervention in the first few weeks post stroke. Laska et al [2] randomised 123 patients with aphasia to receive 45 minutes of SLT a day for 21 days starting within 2 days of stroke onset, or no SLT intervention. Severity of the aphasia was not reduced. A recently completed HTA funded study, ACTNow [3] randomised 170 people in hospital post stroke to SLT intervention for up to 4 months or attention control (conversation with paid visitors). No significant differences between groups were shown. As aphasia persists for many stroke survivors, therapy in the longer term also warrants investigation using adequately powered RCTs. Although rapid spontaneous recovery may occur in the first few months, there is preliminary evidence to suggest targeted and intensive SLT treatments can promote further improvement in the longer term [4,5,6,7].

Targeted therapies with good preliminary evidence to date include: 1) Constraint Induced Aphasia Therapy (CIAT) - use of language in games to make, reject or clarify requests for targeted items for 30 hours over 2 weeks [4,8,9]. A preliminary systematic review of 10 studies conducted over the decade concluded that the evidence for this technique is favourable [10]. Model oriented aphasia therapy (MOAT), which tailors treatment according to patients' individual symptoms, was found to be comparable to CIAT when delivered at similar intensity [11]. Raymer et al 2008 found personal relevance or 'salience' of the language material being practiced to be important when targeting therapy [5]. Robey (1998) found that treatments delivered at more than 2 hours a week resulted in greater change than treatments delivered at less than an hour and a half a week whilst Backheit et al (2007) found no evidence of difference for 5 versus 2 hours of SLT for 12 weeks [12,13]. The Cochrane review of aphasia therapy warns that the more intense the therapy the higher the withdrawal/non compliance [1]. While the optimum intensity remains unclear, it is generally acknowledged that regular therapy practice is a factor in treatment success. The resources required to achieve intensive therapy in the long term is prohibitive in the current financial climate and lower cost options for the support of repetitive, intensive practice are needed. There is evidence that non speech and language therapy professionals can be employed successfully to support therapy activity [3,14]. Computer technology can also provide the potential for supporting intensive treatment in the long term.

Computer therapy developed for the treatment of aphasia has been reported to be useful in the provision of targeted language practice and provides opportunities for independent home practice as part of a self management approach to maximise practice intensity [15,16], improving outcomes for reading, spelling and expressive language [17,18,19]. The Department of Health report, 'Our Health, Our Care, Our Say' (2006) recommends self management for long term conditions supported through technological innovation [20]. However, to date, studies of self managed computer therapy for aphasia have been limited to descriptive case series with only 2 reported RCTs, both for reading treatment [16,21,22]. Although these studies were not fully powered, they indicate potential effectiveness of computer therapy. Such computer based services for long term management of aphasia therapy could provide a low cost therapy option. However, the actual cost effectiveness has not been investigated.

Our StepByStep computerised approach to long term aphasia therapy (detailed in the intervention section) combines current evidence underpinning language therapy with practical considerations of treatment delivery. Skills of a qualified speech and language therapist are used to select individually targeted therapy exercises, computer software is provided for regular self managed practice of therapy exercises, and volunteers support language practice and computer use [23]. We carried out a pilot study evaluating this approach with 34 people with persistent aphasia. They were randomly assigned to using this available computer software designed for treating aphasia, or usual long term care (most frequently this was social support). On average people with aphasia practiced their speech exercises on the computer independently for 25 hours over 5 months. The therapy significantly improved ability to use spoken words when compared to usual care ($P=0.014$). The results indicated that self managed computer therapy supported by volunteers (total of 4 hours on average) could help people with aphasia to continue to practise, improving their vocabulary and confidence talking. Patients and carers found it an acceptable alternative to face to face therapy. Self managed computer therapy could improve the quality of life of people with persistent aphasia, at relatively low cost to the NHS and society [24].

The proposed study builds on the work of the pilot to investigate the clinical and cost effectiveness of using this computer therapy approach to deliver targeted, intensive long term aphasia therapy for word finding in a definitive phase III RCT.

Intervention under study: independent speech and language therapy practice for word retrieval through use of computerised therapy exercises. The computer intervention will be tailored to the individual's needs by a qualified speech and language therapist. Participants will be encouraged to practice daily for at least 20 minutes for a 6 month period. Trained volunteers or speech and language therapy assistants will provide support to motivate practice. This intervention is designed for people with the language disorder, aphasia, acquired a minimum of 4 months prior to randomisation as a consequence of stroke.

Products: The intervention under study makes use of a computer software package called StepByStep© marketed by Steps Consulting Ltd.

Risks and Benefits. This study is not an investigation of a medicinal product (IMP) and entails no invasive procedures. Benefits indicated by the pilot study include greater ability to use language and have conversation and improved confidence. The only risk identified was fatigue.

This trial will be conducted in compliance with the protocol, GCP and regulatory requirements.

2. Aims and objectives

The aim of the study is to provide definitive evidence of the clinical and cost effectiveness of targeted, intensive speech and language impairment based therapy intervention for word finding delivered through self managed computer exercise for persisting post stroke aphasia. This builds on a successful 3 year RfPR funded pilot RCT conducted by this team which informed possible effects, measures, feasibility, recruitment rates, compliance, cost effectiveness analysis and a power calculation. Results demonstrating feasibility are published in Stroke 2012:43; 1904-191 [24].

The World Health Organisation (2001) recommends use of the International Classification of Functioning, Disability and Health (ICF) to describe and evaluate the impact of health problems on a person's life [25]. The first three objectives therefore seek to identify the effect of self managed computer treatment for persisting aphasia on the ICF dimensions of impairment, activity, and participation compared to usual care alone or attention control:

1. To establish whether self managed computerised speech and language therapy for word finding increases the ability of people with aphasia to use vocabulary of personal importance (impairment).
2. To establish whether self managed computerised speech and language therapy for word finding improves functional communication ability in conversation (activity)
3. To investigate whether patients receiving self managed computerised speech and language therapy perceive greater changes in social participation in daily activities and quality of life (participation).
4. To establish whether self managed computerised speech and language therapy is cost effective for persistent aphasia post stroke.
5. To identify whether any effects of the intervention are evident 12 months after therapy has begun.

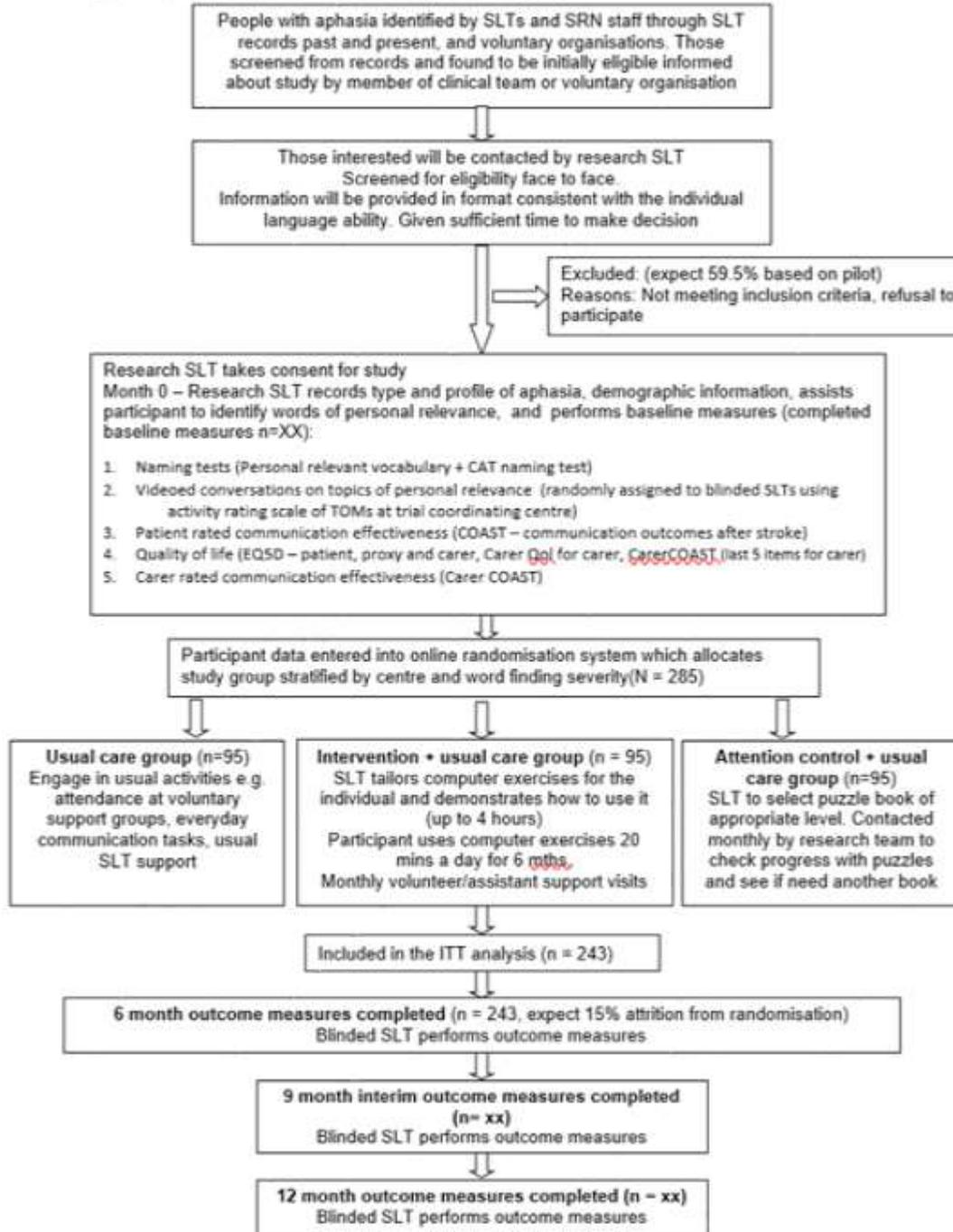
Secondary objectives include investigating the generalisation of treatment to retrieval of untreated words (impairment); the carer perception of communication effectiveness (participation) and the impact on the carer quality of life; and identification of any possible adverse events. The primary outcome time point will be 6 months after randomisation (end of treatment) with further follow up at 9 and 12 months.

3. Trial Design

The study will use a pragmatic, parallel group randomised controlled adjunct trial design – all participants will receive usual care -comparing outcomes for people with persistent aphasia 4 months or more post stroke who are randomly allocated to either:

- 1) Usual care
- 2) Self managed computerised speech and language therapy in addition to usual care
- 3) Attention control in addition to usual care.

Figure 1: Flow of participants through the trial (Consort diagram)



Blinding

This is a single blind study. The patient participants are not blind to their treatment allocation. The SLTs performing baseline assessments will do this prior to randomisation. A second SLT at each site, blinded to group allocation will perform 6, 9 and 12 month follow up assessments as in the pilot study. The SLT setting up the treatment will ask participants not to discuss treatment with the person coming to carry out follow up measures. It is possible that un-blinding will happen during conversation and the SLTs will be asked to record instances of this. A primary outcome is functional communication in conversation. Video recordings of conversations at baseline, 6, 9 and 12 months will be presented in random order to SLTs in the project coordinating centre to rate, blind to treatment allocation and follow up time.

Allocation schedules will be kept centrally and at site. Measures will be taken by sites to maintain blinding of the research SLT who will conduct outcome measures.

Duration

Each participant will be in the trial for 12 months. Participants will be identified and recruited over an 18 month period in total, and 15 months at each site. Each participant will receive their intervention for 6 months with follow ups at 6 months, 9 months and 12 months. Follow-ups should be carried out in the month following each time-point (e.g. 6-7 months, 9-10 months, 12-13 months).

There are no formal statistical criteria for stopping the trial early. Decisions to stop the trial early on grounds of safety or futility (with regard to recruitment) will be made by the Trial Steering Committee. Progress of the study will be assessed against progression criteria after approximately 22 months.

Data Source

Names, addresses and telephone numbers will be previously recorded on NHS databases, along with identification of having had a stroke with resulting aphasia. This only applies to those recruited from NHS caseloads.

5. Selection and withdrawal of participants

Refer to Appendix 1 for flow diagram of identification and first sift for potential participants.

Participant Identification

Participants will be recruited from approximately 20 speech and language therapy departments across the UK, both from current and past patient records and contacts with longer term voluntary support groups. Speech and language therapy departments agreeing to participate in the project will be asked to identify potential participants. The study will also be advertised using posters (to include images selected by the PPI group) in libraries and GP surgeries in each locality so that potential participants unknown to SLT departments and voluntary groups can self-present to the local research team. Potential participants (those identified as having had a stroke, and a diagnosis of aphasia, 4 months or more post stroke, aged 18 years or above) will be contacted by the research speech and language therapist in each local project centre. This person will be a member of the local clinical team. The participant will be sent project summary information letting them know about the study which is followed up by a telephone call 1-2 weeks later to establish whether they are interested in knowing more about the study or not. If they are interested, the research speech and language therapist will make an appointment to visit them at home at a time convenient to the potential participant.

Speech therapy databases will be reviewed to identify potential participants. These databases will usually include personal information such as full name, date of birth, contact details, GP, reason for admission to hospital/speech therapy service etc. This information will therefore only be seen by speech and language therapists who are part of the clinical team treating or having treated these patients and will not be accessed by any members of the wider research team. A screening log will be completed by the therapist who is identifying potentially eligible patients from the database. Data recorded and sent back to the Clinical Trials Research Unit will include unidentifiable information including initials, gender and age. We also wish to collect the post code sector (not full post code) to see if socioeconomic area is a factor in participation. The reason for not arranging an appointment will be captured on the screening log if freely given.

Planned inclusion and exclusion criteria

Participants will be included if:

1. Aged 18 or over
2. Diagnosis of stroke(s)
3. Onset of stroke at least 4 months prior to randomisation
4. Diagnosis of aphasia, subsequent to stroke, as confirmed by a trained speech and language therapist.
5. Ability to score 5-43 / 48 on the CAT Naming Objects sub-test [25] [Mild 31-43, Moderate 18-30, Severe 5-17]
6. Ability to perform a simple matching task in StepByStep© with at least 50% accuracy (score of at least 5/10; to confirm sufficient vision and cognitive ability).
7. Ability to repeat at least 50% of words in simple word repetition task in StepByStep© program (score of at least 5/10).

Participants will be excluded from the study if:

1. They have another pre-morbid speech and language disorder caused by a neurological deficit other than stroke. (A formal diagnosis can be reported by the participant or relatives and confirmed by the recruiting speech and language therapist).
2. They require treatment for a language other than English (as the software is in English)
3. They are currently using the StepByStep© computer program or other computer speech therapy aimed at word retrieval/naming.

Many people post stroke will have physical impairment which makes a standard computer difficult to use. If allocated to the computer intervention, appropriate ways of accessing the computer speech therapy will be provided such as the use of tracker balls, therefore physical disability is not an exclusion criterion. There is no maximum amount of time post stroke for inclusion in this study as treatment efficacy was shown in the pilot study for participants of 10 years and more post stroke.

Refer to Appendix 2 for flow diagram of recruitment and assessments.

Screening for eligibility

At the first visit to the potential participant, before providing detailed information about the study, the research speech and language therapist will confirm whether or not the person is eligible. They will request verbal consent to carry out the naming test of the Comprehensive Aphasia Test [26]. This test is used in routine practice and will establish the severity of the

word finding deficit. If the word finding score is less than 5 (10%), or greater than 43 (90%), an explanation will be given that this type of computer therapy is not suitable for them. They will be thanked for their time but no more information about the study will be provided. If they are still interested in computer based therapies, they can be directed to the aphasia software finder <http://www.aphasiasoftwarefinder.org> (last accessed on 24 Oct 2013) developed to help patients with aphasia identify software that is most suitable for them. If the potential participant has eligible word finding scores, the research speech and language therapist will ask them to have a go at a simple matching task on the computer to confirm ability to see the screen and perform simple tasks.

Recruitment

The level of support required to enable a person with aphasia to provide informed consent is dependent upon the severity and profile of the aphasia. In order to provide information in a format consistent with each individual's language ability, a Consent Support Tool (CST) will be used. In the absence of any other published tool to identify the most appropriate style of information to provide on an individual basis, this consent support tool was developed and refined with the assistance of people with aphasia and their carers' in the Patient and Public Involvement (PPI) advisory group during the pilot study and has been validated in a further piece of work [27]. The research speech and language therapist at each site will request verbal consent from the potential participant to carry out part A of the CST (10 minutes). The result will indicate which style of information they are most likely to understand. Three different styles of information sheet are available to enable as many participants as possible to be involved in their own decision whether to consent to their participation in this study. Patient information sheet 1 is in large print with key words emboldened (for those who can understand written paragraphs). Patient information sheet 2 is for those who can read simple sentences but not full paragraphs. It follows standard aphasia friendly principles with one idea presented per page in short simple sentences of large font. Key words are emboldened and each idea is represented by a pictorial image. Patient information sheet 3 is for those who can understand with significant support. Each idea is presented on a power point slide with simple text, key words emboldened and picture support. Each sentence should be presented in turn by the speech and language therapist, read aloud to the potential participant and supported with gesture, showing objects and drawing. The next sentence is then presented. The consent support tool will also identify individuals for whom carer assent is required (those with severe aphasia who find it difficult to understand information, even with the support of adapted/pictorial information formats). These potential participants will be shown a short video clip of the computer programme being used and of someone working on a puzzle book. Participants will be given sufficient time to consider their participation before informed consent is taken by a research SLT. Participants providing their own informed consent will be provided with an aphasia friendly consent form and asked to initial all boxes before signing. If potential participants with severe aphasia indicate an interest, a relative (in Scotland the person's legal representative or nearest relative) will be asked to read the full information sheet 1 and a covering letter detailing their responsibility, and will be asked to sign a carer declaration on behalf of their relative with aphasia (in Scotland they will be asked to sign a consent form). At the request of the PPI group, all patients will be given a copy of either the standard information sheet or the aphasia friendly information booklet to keep and a picture summary on one side of A4 paper. For those participants with a carer, the carer should be asked if they are willing to complete some outcome measures related to their own quality of life and perception of their relative's communication ability. They should be provided with the carer information sheet detailing their potential involvement and asked to sign a consent form.

Withdrawal

Participants may withdraw from active participation in the study on request. Individuals removed from active participation in the intervention will not be replaced and will be followed up for all outcome information unless they also request no more follow up. Reason for withdrawal from the intervention, if known, will be recorded on a CRF.

6. Randomisation and enrolment

After signing the consent form, and following baseline assessments, the participant will be randomised to one of the three trial intervention arms. Randomisation will be performed by an online randomisation system developed and maintained through the Sheffield CTRU. The randomisation sequence will be generated in advance by the trial statistician. Randomisation will be stratified by centre (as heterogeneity between centres is expected), and according to severity of word retrieval based on percentage scores on the naming test of the Comprehensive Aphasia Test (Mild 31-43, Moderate 18-30, Severe 5-17). The research speech and language therapist who took the consent will either enter the participant demographic details, word finding severity, recruitment centre and confirmation of consent directly onto the randomisation system (if internet access easily available), or will contact the central trial team at the University of Sheffield by telephone and provide these details for a member of the core team to enter into the randomisation system. The research speech and language therapist will then inform the participant which group they have been allocated to and draw their attention to the description of this group in the information sheet.

7. Trial treatment

1. Usual care control arm

Usual care for this pragmatic study may consist of participation in a range of activities to a greater or lesser extent. Usual care varies across the country in terms of type, frequency and length of provision, and is dependent upon available resources in each locality. Findings from the pilot study confirmed that usual care four months or more following a stroke may include the following:

1. Face to face speech and language therapy support focussing on assistance with compensatory strategies, provision of communication aids or psychological support with adjustment to the aphasia.
2. Attendance at support groups such as Stroke Association 'Communication support groups', Chest Heart and Stroke Scotland's Voluntary Support Service groups, peer support groups, groups organised by other charities/voluntary organisations.
3. Informal communication support provided through conversation with family and friends.
4. Some people may still receive speech and language therapy interventions targeting the language impairment itself (reading, writing, speaking, and understanding) in some areas of the country but this was not evident in the 84 people assessed for eligibility in the pilot.

Those who are randomised to the usual care group will not receive any project specific intervention. Usual care will be recorded on the baseline CRF.

2. *Self managed computerised therapy intervention*

A structured intervention is proposed in addition to usual care as tested in the pilot study. The intervention targets word retrieval as it is one of the challenges most frequently experienced by people with aphasia, restricting their communication. The intervention was designed by speech and language therapists specialising in aphasia intervention and use of computer software for treatment. The three key components of the intervention were designed to incorporate key factors that research suggests positively influence aphasia therapy outcomes combined with practical considerations:

1. Qualified SLT assessment of participant's language profile to tailor computer exercises using the StepByStep© software (version 5) so that they target the specific language deficit identified. Creation of exercises using target words of personal relevance to the participant.
2. Daily independent word finding practice with the tailored computer exercises by the participant for 6 months.
3. Volunteer/SLT assistant support to enhance adherence to the computer exercises and to encourage transfer of new words into functional daily situations.

1. *Qualified speech and language therapist assessment, tailoring of exercises and monitoring:*

The research SLT (one at each site) will tailor computer exercises to the individual using 100 words of personal relevance chosen by the participant. There is a large bank of photographs within the computer programme and if something extra is required (e.g. picture of a family pet, grandchild, or favourite football team) it can easily be photographed digitally and added by the SLT. The computer software [28] enables the SLT to select exercises using these words that follow steps in the therapy process that the therapist would take if delivering it face to face. The SLTs delivering this intervention will receive training on how to set up appropriate exercise steps during the site initiation visit. The SLTs base the selection of exercises on language skills demonstrated in the initial language assessments. To maintain fidelity of the intervention, they will be shown the therapy manual accompanying the StepByStep computer therapy approach, and to evaluate fidelity they will record which exercise steps are selected based on the skills identified. The SLT will provide initial demonstration of the software exercises and spend up to 2 hours (spread over 2-3 sessions) checking that the individual is able to use the software and monitoring the appropriateness of the tailored exercises. The SLT will also review the need for additional pieces of hardware such as tracker balls in order to make it physically possible for participants to use the computer.

2. *Regular self managed practice*

The participant will then be asked to work through the exercises on the computer aiming to practice each day for 20-30 minutes. Participants will be given a 6 month period to work through the therapy material on the computer and practice using the new vocabulary in their daily lives. Practise with the computer for a minimum of 20 minutes 3 times a week at home on average across at least a four month period will be considered per protocol. The amount of practice will be captured automatically by the computer programme. This is less than the 2 hours a week of therapy suggested to be minimally effective practice intensity in the literature, but accounts for periods of illness and holiday expected to occur in a 6 month period. As this is a pragmatic trial, those participants who have the software installed on their own

computers will not be prevented from continuing to practice if they wish, following the 6 month supported intervention time. If computers were loaned, they will be taken back after 6 months to give to a new participant (as permanent loan of equipment would be unusual in practice).

3. *Volunteer support to assist with treatment adherence and carry over into daily activity*

To enhance treatment compliance, the SLT will provide training to local volunteers who already have a working relationship with the SLT department (based in NHS trusts, local voluntary organisations, or student SLTs) or SLT assistants based in the department. They will use the 3 hour training programme and instruction book developed and evaluated during the pilot study. The volunteer will be asked to visit the participant for a minimum of 4 hours (the recommendation will be once a month for an hour, or every two weeks for half an hour (to suit the patient), carrying out the following tasks:

1. provide technical assistance
2. observe and encourage use of computer exercises
3. check results and discuss difficulties
4. assist participant to move on to harder tasks in the therapy process pre-programmed by the SLT
5. encourage the use of new words in everyday situations through conversation and discussions with family about how to encourage use
6. set up new vocabulary sets if all 100 words have been completed

The participants will be able to contact the volunteer/SLT assistant by telephone for technical advice on computer use between planned visits if necessary. Volunteers/SLT assistants will be invited to meet together with their peers and the research SLT for an hour every two months for support and discussion of issues arising and new practice material required by their participant. After each planned visit to the participant the volunteer/therapy assistant will complete a feedback form giving the SLT feedback on what they did in the session, what went well/not well and any issues/questions. The volunteer may contact the SLT by e-mail or telephone between support sessions to report any concerns/difficulties.

The majority of the practice time involved in the intervention is self managed by the participant through regular use of the aphasia computer software. As described above, the intervention will be tailored, initiated and monitored by a speech and language therapist (approximately 4 hours therapy time in total), and supported by volunteers/ SLT assistants (minimum 4 hours face to face contact time). These times are based on averages found in the pilot study. The SLTs, SLTA's and volunteers will be asked to keep diaries of resource use showing direct and indirect (telephone, computer set up) time spent and therapist grade. If a participating SLT department has existing access to the StepByStep telehealth module, therapists or therapy assistants could use this as a source of monitoring which will be recorded as indirect time spent. Therapists will limit this method of monitoring to once every two weeks. Resource use will include the cost of the software. This will be installed by the SLT on participants' home computers. If any participant does not have access to a computer, the software will be loaned on a project lap top. In the pilot study, 50% of participants needed to borrow a lap top, therefore each of the 20 recruitment centres will be asked to make 2-3 lap tops available (5 are expected to be randomised to the intervention at each site). Some departments have existing lap tops. If departments need to purchase lap tops for the purpose of treatment in the study, the cost would need to be met through excess treatment costs. A small number of lap tops will be made available for loan from University of Sheffield for centres where particular difficulties are encountered.

3. Attention control arm

The third group in this study intends to control for the potential impact of elements of the intervention which of themselves do not provide or require specific speech and language intervention.

Participants randomised to this arm will be provided with generalised non language based activities to carry out and general attention in addition to usual care. On allocation to this group, the SLT conducting baseline assessments will provide books of standard puzzles that can be purchased from most supermarkets or high street shops. Each book will contain enough activities for one to be carried out each day for at least a month. Examples of puzzles include getting through a maze, spotting the difference between pictures, matching objects that are the same, games of noughts and crosses, word searches etc. The SLT will provide age appropriate puzzle books that match the participant's linguistic and cognitive ability as indicated by the baseline assessments. Puzzle books will be colour coded into levels of easy, medium and hard by the clinicians on the research team centrally and a leaflet will be provided to give SLTs guidance on skills required for each level.

A member of the research team will contact the participants or their carer by telephone or e-mail (whichever is preferred by the participant) once a month to mimic the attention provided by volunteers in the intervention arm. They will ask if they are enjoying the activities, how many they have managed to do, whether they would like a new puzzle book sent to them for the coming month and whether they would like the same level of difficulty or an easier or harder one. The participants will also have access to these contact details to enable them to ask for easier or harder books at any time if necessary, again, mimicking the access to the volunteers/SLT assistants and type of attention available in the intervention arm.

The StepByStep© software is central to the intervention described in section 3. The software is produced by Steps Consulting Ltd. As the software constitutes an excess treatment cost, it will be purchased from Steps Consulting Ltd by the NHS trusts acting as study sites. Each participant in the intervention arm will be provided with the software and the SLT will install it on their own computer or one loaned by the NHS trust or project team. Installation is by CD Rom or data stick.

4. Evaluation of intervention fidelity

Evaluation of intervention fidelity requires assessment of intervention adherence as well as other factors that moderate adherence such as quality of delivery and participant responsiveness [29]. As a complex intervention it is vital that we understand how the StepByStep approach is being delivered in the Big CACTUS trial.

Existing data collection to inform fidelity assessment

As this is a self-managed intervention, adherence of the participants in using the intervention as intended will be monitored through volunteer or assistant visits with reminders to practise daily and assistance with using the full range of exercises set. The speech and language therapist will also monitor practice through feedback provided by the volunteer or assistant and record the time period in which the software was available for the participant. In addition, the software will automatically capture the amount of practice on a key file which will be returned to the study coordinating team centrally to be reviewed for total practice time and patterns of practice (see page 18).

Information about adherence of the SLT and volunteer/ therapy assistant delivering the intervention will be collected through diaries of direct and indirect time spent with the

participant (see page 24) including session number, duration and content. The speech and language therapists delivering this intervention will receive training on how to set up appropriate exercise steps. To enable monitoring of the intervention fidelity, they will be asked to complete a checklist which guides their selection of exercises based on the participant language profile identified during assessment. These will be reviewed centrally by the study quality monitor. The key files from the participants' software will enable comparison of a random selection of exercises provided with the corresponding checklist completed.

Additional data to be collected to inform fidelity assessment

In a separate study with key stakeholders about the StepByStep approach it has been suggested that some additional measures should be added to explore how the intervention was delivered and received.

The knowledge and skill of the SLT in conducting the trial and delivering the intervention has already been assessed by a quiz completed 5 months after they randomised their first participant to check learning from the training. However, in order to explore changes in the therapist's knowledge about the intervention over time we will also ask them to complete the intervention section of the quiz at 10 and 15 months. An information sheet will be provided informing the SLTs how we intend to use the information from the 10 and 15 month time points, and retrospectively from the 5 month time point. Participants will be asked to sign and return a consent form if they are willing to participate.

The volunteers/therapy assistants' relationship with the participant is a key component of the intervention as they will be the main source of support during the intervention. Collecting data directly from the participants with aphasia would be the most reliable way of measuring this relationship, but due to the complexity of existing alliance scales they would not be suitable to use with this population. As such the volunteers/therapy assistants will be asked to complete the Working Alliance Inventory – Short Revised – Therapist (WAI-SRT) version after their three month visit (e.g. if visiting once a month after 3rd visit, but if visiting once every two weeks after 6th visit) to the participant [30]. An information sheet will be provided prior to their completion of the WAI-SRT to ensure that they understand how their data is being used and they will be asked to sign and return a consent form if they are willing to participate. The alliance scale can be sent back to the research team directly by the volunteer/therapy assistant or it can be returned via the SLT.

Three additional questions will be added to the patient diary, which is there to record any difficulties or negative impacts of the intervention (see table 1, page 24), on the third occasion it is sent out (e.g. 3 months into the intervention period). Reading the questions will require a certain level of written understanding, as such they will only be sent to participants who have a carer involved in the study or demonstrated written understanding of 3 key words or more on the Consent Support Tool. The questions are about difficulties that might impact on the patient's adherence to the intervention, including: 'how motivated are you to practise your StepByStep computer therapy excises?', 'how easy is it to use the StepByStep computer therapy?' and 'are the words on the StepByStep computer therapy words you want to say?'. Participants will be asked to circle how they feel on a visual analogue scale from 1-10. There is a box to be selected by the carer/relative if they are completing it on behalf of the participant. The Big CACTUS patient and public involvement (PPI) group contributed to the development of the additional questions deciding which pictures and wording would best help them to understand the questions.

Analysis of intervention fidelity

Descriptive statistics will be used to present the results of the fidelity evaluation detailing the level of participant, SLT and volunteer/therapy assistant adherence and other potential moderators of adherence, such as therapist skill, volunteer/assistant alliance and motivation. Analysis will be conducted to explore the baseline characteristics (e.g. age) associated with participant adherence to the intervention to inform guidelines for clinicians about who can manage intensive therapy practice using the StepByStep approach. In addition, to contribute to the continued development of the StepByStep approach a component analysis will be conducted to identify the essential components of the intervention, by exploring which components of the intervention (practice time, motivation, alliance between volunteer/therapy assistant, etc.) are associated with a positive primary endpoint.

8. Assessments and procedures

Outcome measures

Primary

1. The change in word finding ability of words personally relevant to the participant will be measured by a picture naming task (100 words with a maximum of 2 points each). The word finding score will be expressed as a percentage of the total score and change in the percentage 6 months from baseline will be calculated.

2. Change in functional communication will be measured by blinded ratings of video recorded conversations between a SLT and participants, using the activity scale of the Therapy Outcome Measures [31]. Conversations will be structured around topics of personal relevance to the participants by the SLT performing baseline measures to ensure sensitivity of the measure. The same topic guide will be followed by blinded SLTs performing outcome measures. Independent SLTs blinded to treatment allocation and measurement time point will rate the videoed conversations at the project coordinating centre. We will carry out a benchmarking session using the TOMS with potential raters to get consensus as to how the TOMS will be used in this project, followed by inter and intra rater reliability tests using 10 practice videos. Raters selected for final rating of all participant videos will have intra rater reliability of at least 70% practice videos rated within 0.5 between time 1 and time 2, and inter-rater reliability of at least 70% videos rated within 0.5 of the median scores at both time points. Refer to separate document 'Process for selection of TOMS raters and scoring procedure October 2016' for additional detail.

Key secondary

Improvement in patient perception of communication will be measured using the COAST at 6 months - a patient reported measure of communication related activity, participation and quality of life validated for evaluating SLT interventions in the HTA ACTNoW project [32].

Other secondary

Evidence of treatment effect will be measured by repeating all outcome measures at 9 and 12 months from baseline in addition to the primary end point of 6 months. The 9 month time point is included as an interim measure as withdrawal from the study was found to increase over time in the pilot study.

Big CACTUS

Use of learnt vocabulary in the context of conversation will be measured using a checklist of target words during rating of the videoed conversations.

Generalization of treatment to retrieval of untreated words will be measured using the naming test from the Comprehensive Aphasia Test.

Carer perception of communication effectiveness will be measured using the Carer COAST [33]. Adverse events/effects of treatment will be reported through diaries.

Cost effectiveness

A cost-utility analysis will be undertaken from the NHS and personal social service (PSS) perspective. The cost effectiveness outcome will be the incremental cost effectiveness ratio, where effectiveness is measured in quality adjusted life years (QALYs). The incremental analysis will include all three of the trial arms. Resource costs will be estimated for patients including intervention software and hardware, and SLT input time, combined with standard costing sources. Volunteer time will also be recorded and costed for inclusion in a supplementary societal analysis.

The EQ5D will be administered at all time points and combined with standard valuation sources to measure QALYs gained in each treatment arm. An accessible version of the EQ5D designed and tested for people with aphasia in the pilot study will be completed by participants and the carers will complete the standard version by proxy. Carers will also complete the EQ5D carer, the last five items of the CarerCOAST, and CarerQoL for themselves as indicators of their quality of life.

Table 1. Summary of outcome measures

Outcome	Measure	Participant time	Method of collection
Change in word finding ability	Naming of 100 personally relevant words	30 mins	Taken at baseline by research SLT recruiting participant prior to randomisation. 6, 9 and 12 months by blinded SLT.
Change in functional communication	10 minute videoed conversations structured around topics of personal interest. Activity scale of TOMS used to measure conversational ability	10 mins	Conversations at baseline by research SLT, Blinded SLT follows same topic guide at 6, 9 and 12 months. Videos randomised and rated centrally by blinded assessors.
Change in patient perception of communication & quality of life	COAST self reported questionnaire.	10 mins	Administered by research SLT at baseline, blinded SLT at 6, 9, and 12 months.
QALY's for cost effectiveness	EQ5D for patient and carer (accessible, carer and by proxy)	10 mins	As above

Generalisation to untreated words	Naming test from Comprehensive Aphasia Test	15 mins	As above
Carer perception of change in communication	Carer COAST (first 15 items)	8 mins	As above
Carer quality of life	CarerCOAST (last 5 items)	2 mins	As above
Carer quality of life	CarerQoL	10 mins	As above
Negative effects of treatment	Patient diary to record any difficulties, negative impacts of intervention		Patients/carers – central team to send monthly letter reminding to send back in prepaid envelope.

Data recorded during intervention period

Initial assessment will be performed by the local research SLT once informed consent has been given. This will include collection of demographic data: aphasia type, age, gender, time post onset of stroke, and type and location of stroke (if known). Numbers of personally relevant words named correctly in response to picture presentation will be recorded. Pictures from the naming test of the Comprehensive Aphasia Test, not used in therapy, will be presented and the number named correctly will be recorded. Scores will be used to identify baseline naming severity for the stratified randomisation. Conversation topics will be identified from personally relevant vocabulary. A conversation of approximately 10 minutes will be video recorded. The topics and questions asked by the SLT in the baseline conversation will form a topic guide to be used in follow up conversations. Participants and carers will be asked to complete the COAST and carer COAST respectively as a measure of their perception of communication and quality of life. The participants will be asked to complete the accessible version of the EQ5D and the carers will complete the standard EQ5D by proxy, as well as the EQ5D carer, the last five items of the CarerCOAST and the CarerQoL for themselves as indicators of quality of life.

Randomisation to treatment group will follow baseline assessments. During the intervention period, SLTs and SLTA's involved with the participants in all groups will be asked to complete a diary of direct and indirect time spent with the participant. Participants will be asked to complete monthly diaries reporting any adverse effects of the intervention.

All outcome measures will be repeated at 6 months (treatment end), and approximately 9 and 12 months from baseline to identify long term intervention effects. As the dropout rate increased after treatment end in the pilot, the primary outcome will be at 6 months. Follow-ups should be carried out within one month of each time-point.

A 3 month phone call (or visit if more appropriate) will be made by the PI to the participant to record usual care and adverse events or serious adverse events from the participant's perspective, in the last three months.

Procedures for withdrawal from the trial treatment or from the study

The participant/carer will inform the local research speech and language therapist if they want to discontinue the intervention. Regardless of the fact that participants are withdrawn from the trial treatment, every attempt will be made to follow up the participants unless

they specifically request withdrawal from the trial. Data collected up to this point will be included and analysed.

Discontinuation of treatment

If the participant becomes ineligible (for example due to a further stroke), they will be asked if they wish to continue participating in the study. If the participant no longer has the capacity to make that decision themselves, their carer/relative (in Scotland Legal Representative/nearest relative) will be asked to help make that decision after re-reading the information sheet. They will be asked to provide a signed carer declaration (in Scotland a signed carer consent form) following the same process set out for recruitment of participants lacking capacity. The participant will continue to be followed up unless they request otherwise. If the participant does not wish to continue or a carer cannot provide a signed declaration (in Scotland signed consent) in the event of loss of capacity, the anonymised data collected to that point will be retained for analysis but no more data will be collected.

Procedures for attempted follow-up of participants "lost to follow-up"

Participants will be considered lost to follow up if the local research speech and language therapist or the therapist conducting outcome measures fails to make contact to arrange an appointment after a minimum of 4 attempts (over a 4 week period). This applies to all baseline and outcome time points following written consent.

Site & Trial Closure Procedures

The end of the trial is defined as completion of all follow-up data collected and monitoring for the last visit of the last participant. At the point at which all CRF's have been collected and entered (or centres have failed to respond despite reminders) and all data have been entered and cleaned, closure of the database will be approved.

Safety assessments

Adverse events associated with the intervention are not anticipated given the low risk intervention (in line with similar studies managed by CTRU). However, if adverse events do occur these will be recorded by the therapist on the CRF and database. Adverse events do not need to be reported by fax to the CTRU.

Adverse events may include: increased fatigue, fits or seizures, worsening vision or visual difficulties, increasing frequency or severity of headaches, accidents (e.g. falls) or injuries.

If a hospital admission, or any other event considered serious occurs, these will be reported as Serious Adverse Events (SAEs). We will not report further stroke related events as SAE's as these are expected within this population.

The following criteria will be used when assessing SAEs:

Intensity (severity):

1. Mild - does not interfere with routine activities
2. Moderate - interferes with routine activities
3. Severe - impossible to perform routine activities

Relationship to the trial activity (Computerised speech therapy or puzzle books):

1. Unrelated - There is no evidence of any causal relationship.

2. Unlikely - There is little evidence to suggest there is a causal relationship. There is another reasonable explanation for the event (e.g. the participant's clinical condition).
3. Possible - There is some evidence to suggest a causal relationship. However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition).
4. Probable - There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
5. Definite - There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.
6. Not assessable - There is insufficient or contradictory information which cannot be supplemented or verified.

Reporting procedures

SAEs will be reported in accordance with the CTRU Standard Operating Procedure PM004 Adverse Events & Serious Adverse Events.

The Principal Investigator (PI), or delegated investigator, is responsible for reporting all SAEs to CTRU in Sheffield by fax within 24 hours of discovering the SAE. All SAE forms will be stored in the Site File.

The CTRU will inform the Sponsor and CI, who are responsible for assessing the seriousness and reporting to relevant regulatory bodies, where appropriate. Serious Adverse events should be reported by the CTRU to the Head of Department/School, using the Sponsor's adverse event report form, as soon as possible and normally within 5 working days. A copy of the report should be kept in the Trial Master File for reference and a copy sent to the Head of Operations Section, Research and Innovation Services.

If an SAE is categorised by the PI/CI as related and unexpected the REC must be informed within 15 days of CTRU being alerted. This is the responsibility of the Trial Manager at the CTRU, or delegated person in their absence. This should be reported to the REC using the Safety report form for non-CTIMPs (Clinical Trial of Investigational Medicinal Products).

Reporting SAEs to relevant bodies will be conducted by the CTRU and will be documented in the Trial Master File. AEs and SAEs will be reported regularly in data reports to the oversight committees.

Participants using the computer intervention will also be recording any perceived negative effects in a diary which will be returned to the CTRU on a monthly basis and recorded on the CRF. This will be reviewed periodically by the Chief Investigator who will contact the local PI if considered clinically important (e.g. fatigue from computer use).

9. Statistics

Sample size:

The study aims to recruit 285 participants across 20-24 speech and language therapy departments (study sites/centres). The target for each site is 15 participants in total with 5 randomised to each of the three study arms.

The sample size of 285 patients in total (95 per arm) is the maximum sample size estimate across the two primary endpoints (word finding ability and functional conversation) and key secondary endpoint (patient perception of communication ability) for 90% power and a two sided significance level of 5%.

Assumptions for the sample size calculation:

For improvement in word retrieval the estimated effect size is 10%, with a standard deviation (SD) of 17.38%, from an analysis of covariance (based on results of the pilot study). For assessment of conversation the estimated effect size is 0.45 of a SD (with a correlation between baseline and outcome of 0.5 previously observed in the ACT NoW study). For patient-rated improvement using the COAST questionnaire the estimated effect size is 7.2, with a standard deviation (SD) of 13.5 (with an assumed correlation between baseline and outcome of 0.5). The observed dropout rate was 5 out of 33 (15%; 95% CI: 5 to 32%) in the pilot study, which translated to a completion rate of 28/33 (85%; 95% CI: 68 to 95%) [34].

Internal pilot

The initial phase of the study will be conducted as an internal pilot trial and will include clear criteria to inform decisions about progression. Data from the internal pilot will be included in the final analysis. The criteria will include features recommended by the NIHR HTA who have funded this research (e.g. recruitment as a percentage of full study recruitment targets and retention in follow up).

The internal pilot trial will be limited to six sites (>25% of the total), representative of the sites which will be in the substantive study. However, during this phase we will recruit and commence set up processes for all the intended sites. To limit the site set up to the internal pilot trial centres only would result in a delay of many months for the full study if it were to continue, with significant associated additional cost.

In accordance with the guidance on progression rules for HTA internal pilot trials the lag phase expected before recruitment reaches the target rate will be excluded. For the substantive study the lag phase includes the period for obtaining approvals, site recruitment and staff training. The progression criteria will be reviewed 8 months from site set-up of the 6th site in the internal pilot trial. We are estimating that this will be approximately 22 months from contract start.

Based on recruitment rates from the previously published pilot study we will aim to recruit participants at an average rate of 1 participant per site per month. At the end of the internal pilot trial phase the 6 pilot trial sites will have been recruiting for a minimum of 8 months. The progression will be based on achieving the following criteria:

Numbers recruited: The target for these 6 sites will be 36 participants. The progression target for numbers recruited from these 6 sites will be 30. This will be equivalent to the number recruited in total in our previous pilot study and will enable comparison with previous recruitment rates to confirm whether our projections for the substantive study are accurate. There will also be information available from other sites which have completed set up and started to recruit by 22 months, therefore we expect at least 40 participants to have been recruited by the end of the internal pilot phase in total.

Recruitment as % of full study recruitment targets: At the end of the internal pilot trial, progression will depend on having recruited 30 participants i.e. 10% of the total population recruited from 25% of the sites (NB this is only midway through the recruitment phase for these sites). If we only achieve this number, we would be on line to recruit only 80% of the sample size within the study period. We would then bring on the additional 4 contingency sites which are included in the costs to raise the recruitment to the sample size. If we did not meet this number it would indicate that the larger study was unlikely to be feasible.

Retention to first outcome measure time-point at 6 months (primary outcome): The sample size calculation is based on an attrition rate of 15% at 90% power. The progression criterion for retention will be set to ensure a minimum power of 80%. This will be achievable with a retention rate of 65% which will still ensure that the results are generalisable. In the pilot study, the retention rate was 85% with a 95% confidence interval of 68% to 95%. Thus, 65% is outside of the confidence interval from the pilot study.

Identification and retention of volunteers: Sites can provide support to patients in the intervention arm of the trial from paid speech and language therapy assistants or volunteers. Use of volunteers will be reviewed at the end of the internal pilot phase. It is expected that all participants in the intervention arm will be offered support from a volunteer who continues to provide the support for 6 months. Progression criteria for continued use of volunteer support will be set at 80% of participants having been offered a volunteer and 70% of participants continuing to be supported by the same volunteer for their 6 month treatment period. If these progression criteria are not achieved, continuation of the study will be with paid assistant support only.

In summary, 8 months after set up of the 6th site, our progression criteria indicating feasibility of the full trial will now be:

1. Recruitment of no fewer than 30 participants (10% of the target for the full trial)
2. A minimum retention rate of 65%

Patients with at least one post randomisation observation will be included in the analysis. Missing data will be described using summary statistics. All data collected will be summarised as appropriate. Data will be checked and cleaned prior blind to the actual treatment allocation. Data checking will be conducted throughout the study and prior to any analysis of the data.

Analysis

Primary and key secondary endpoints will be analysed using a multiple linear regression model adjusted for baseline measures and stratification factors. Treatment comparisons (Intervention vs Usual Care and Intervention vs Attention Control) will be based on Hochberg testing procedure to allow for an investigation of all three endpoints (co primary and key secondary) whilst maintaining the overall Type I error at 5% [35].

Significance will be declared for the comparison of Usual Care to intervention if and only if both primary outcomes, word retrieval and conversation, are significant at the 5% level or if either comparison is significant at 2.5%.

If and only if significance is declared for both primary outcomes, a similar comparison of Attention Control to intervention will be made. Significance will be declared for the comparison of Attention control to Intervention if and only if both word retrieval and conversation are significant at the 5% level or if either comparison is significant at 2.5%.

If and only if significance is declared for the comparison of Attention Control to Intervention for both comparisons will the key secondary outcome measure (Patient perception of communication and related quality of life, measured using COAST rating scale) be used in a further comparison of Usual care to intervention. If and only if this comparison is significant at the 5% level will intervention be compared to attention control based on COAST.

Diagram 1. Schematic diagram of statistical testing procedure

Intervention to usual care	Hochberg at 5%	Conversation		Word Retrieval
Intervention to Attention control	if both rejected at 5% test this with Hochberg at 5%	Conversation		Word Retrieval
Intervention to usual care	if all 4 above significant at 5%		COAST	
Intervention to Attention control	if all 5 above significant at 5%		COAST	

Primary analysis will take an intention to treat approach (ITT) for all key measures and further exploratory analysis of participants who complied with the intervention will be undertaken using the same statistical tests according to the per protocol principle (PP). The primary time point is 6 months. Only patients with post randomisation observations will be included in the primary analysis at 6 months. As a sensitivity analysis responses will be imputed as appropriate with details provided in the statistical analysis plan.

For the change in word finding (expressed as a percentage) at 6 months from baseline, the measure of intervention effect will be the mean difference in change in word finding ability between the Intervention and Usual Care groups, and the Intervention and Attention Control groups. A multiple linear regression model adjusted for baseline word finding ability and stratification factors (centre and severity of word finding) as fixed effects (39).

The outcome will be modelled as a function of:

- word finding ability at baseline,
- treatment group (Usual Care, Attention Control, Intervention),
- centre as a fixed effect and,

- the severity of word finding as a fixed effect (mild, moderate, and severe).

Results will be reported and presented as adjusted mean difference in word finding ability between the Intervention and Usual Care groups, and the Intervention and Attention Control groups, and Attention Control and Usual Care (for exploratory), with its associated 95% CI and associated P-value.

Improvement in functional communication at 6 months assessed using activity domain of the TOMS, which is a co-primary endpoint will be analysed in the same manner as for the change in word finding ability but adjusted for baseline functional communication (rather than the change in word finding ability at baseline) in addition to stratification factors. Likewise, the endpoints at 9 and 12 months and other continuous outcomes will be analysed using a similar approach for exploratory purposes.

Key subgroup analysis

Analysis will be carried out on key subgroups:

1. Severity of word finding difficulty
 - Mild 31-43
 - Moderate 18-30
 - Severe 5-17
2. Length of time post-stroke

The research team will undertake a blinded review to determine the groups by plotting the primary outcomes against length of time post-stroke.
3. Baseline comprehension ability based on the CAT sentence comprehension scores
 - Within normal limits 27-32 (based on CAT cut off score for normal/aphasic)
 - Mild comprehension impairment 18-26
 - Moderate comprehension impairment 9-17
 - Severe comprehension impairment 0-8

(0-8 = inconsistently understanding at 2 Information Carrying Word (ICW) level; 9-17 = consistently understanding at 2-3 ICW level/simple sentence structures but not complex sentence structures; 18-26 = some understanding of complex sentence structures but not consistent.)

Economic analysis

A cost-utility analysis will be undertaken from the NHS and personal social service (PSS) perspective. Due to the use of volunteers to help participants with their use of the computer program we will undertake a supplementary analysis taking a societal perspective. Costs will be estimated for individual patients including intervention costs and SLT support and co-ordination time combined with standard costing sources [36]. In the pilot study we collected other resource use data (on, for example, GP and hospital visits and prescribed medications) via patient and carer diaries but these did not show important differences between

treatment groups and we will not collect such data in the full trial. The EQ5D questionnaire will be administered at every data collection time point and will be combined with standard valuation sources to measure the quality adjusted life years (QALYs) gained in each treatment arm [37]. An accessible version of the EQ5D designed for people with aphasia was trialled in the pilot study. This has not been validated but represents a way in which EQ5D scores can be elicited directly from patients. We will administer this version of the EQ5D alongside the standard version which will be completed by carers (where the participant has a carer) by proxy. EQ5D and CarerQoL scores will also be elicited from carers, and a life satisfaction question will be included.

We developed a Markov model to estimate the cost-effectiveness of the computer intervention alongside our previous pilot study. Model parameters were informed by clinical data from the trial. We estimated that the intervention was likely to be cost effective, with an incremental cost effectiveness ratio (ICER) of £3,058 per QALY gained, however results were uncertain and the value of obtaining further (perfect) information was very high (EVPI was approximately £37 million). This model will be updated with data from the full trial. The third "attention control" group will be added to the model. Differences between costs and QALYs in the three groups will be described and an incremental analysis will be performed with ICERs calculated. Probabilistic sensitivity analysis will be undertaken to allow the production of cost-effectiveness acceptability curves [36] and value of information analyses [38].

10. Trial supervision

The University of Sheffield will act as sponsor for the trial. Two committees will be established to govern the conduct of this study: the Trial Steering Committee (TSC), and the Trial Management Group (TMG). These committees will function in accordance with Sheffield CTRU standard operating procedures.

The TSC will consist of an independent chair with clinical and research expertise in the topic area, and two other topic experts as the sponsor sees fit and as agreed by the grant awarding body. The TSC will meet at least every 6 months with more frequent meetings as necessary to supervise the overall conduct of the trial in accordance with SOP GOV002, and to monitor safety.

A part time CTRU Trial Manager and part time Speech and language therapist trial coordinator will contact the Chief Investigator and meet with the Assistant Director of the CTRU at weekly intervals while co-ordinating the trial. The TMG will meet at least at three-month intervals and will consist of: the Chief Investigator, the project collaborators, the trial managers and the study statistician. The TMG are accountable to the trial steering committee for the implementation of the trial and entails monitoring of the trial recruitment, data management, randomisation, patient safety, delivery of intervention, adherence to protocol, timescale, and budget management in accordance with SOP GOV001.

A separate PPI advisory group will meet approximately every 3 months. This group will consist of people with aphasia and their carers, and be facilitated by the speech and language therapist trial coordinator and the research assistant. Their role will be to assist with the design of patient information sheets, make recommendations regarding patient recruitment, assist with the lay interpretation and presentation of results and represent the study in the public domain. Due to the nature of the communication difficulties experienced by this group, attendance at the TSC and TMG where the conversation is fast paced and

academic is likely to be uncomfortable and unproductive. Meeting separately means discussions of topics relevant to the study can be carried out slowly with support of a trained speech and language therapist. The speech and language therapist coordinator will attend the TMG and TSC to feedback from this group.

In-house monitoring will be carried out by the research team at the central office in line with the Data Management and Monitoring Plan CTRU Standard Operating Procedure DM009.

11. Data handling and record keeping

Data management will be provided by the University of Sheffield Clinical Trials Research Unit (CTRU) who adhere to their own Standard Operating Procedures (SOPs) relating to all aspects of data management including data protection and archiving. Data entry onto a remote web-based data capture system will be completed by the research team at the central office or by research SLTs at participating sites. Data quality is the responsibility of the Sheffield CTRU Trial Manager and the CTRU Data Management Team. The detailed data management and data quality issues will be set out in a data management and monitoring plan (DMMP) in accordance with CTRU SOP DM009.

Participant confidentiality will be respected at all times. Completion of the case report form/s will be the responsibility of the PI at each participating site. Participant names and contact details (including personal address, email and telephone numbers) will be entered on the study database by the PI. This resides on Sheffield University's Clinical Trials Research Unit in-house data management system. The system uses industry standard techniques to provide security, including password authentication and encryption using SSL/TLS.

Access to the system is controlled by usernames and encrypted passwords, and a comprehensive privilege management feature can be used to ensure that users have access to only the minimum amount of data required to complete their tasks. This can be used to restrict access to personal identifiable data.

Only members of the central research team who are responsible for contacting participants (for example, to send out puzzle books and newsletters) will have access to these details. Patient identifiable data on CRFs will be transferred between the research site and the co-ordinating centre (University of Sheffield) in order to perform data entry and to undertake additional research and monitoring activities set out in the Statistical Analysis Plan (SAP) and DMMP. Original CRFs will be retained in the investigator site file.

Data will be collected and retained in accordance with the Data Protection Act 1998. Anonymised trial data will be entered into a validated database system designed to a specification agreed between Sheffield CTRU and the Chief Investigator. The system will be accessible remotely via a web browser, with the data stored securely on a central server. Access will be controlled by the use of assigned logins and encrypted passwords. The system will have a full electronic audit trail and will be regularly backed up. Quality control procedures will be applied to validate the trial data. Error reports will be generated where data clarification is required. Output for analysis will be generated in a format and at intervals to be agreed between Sheffield CTRU and the Chief Investigator. Trial documents (paper and electronic) will be retained in a secure location during and after the trial has finished in accordance with CTRU SOP PM015 Study Files and Filing.

Archiving

All source documents will be retained for a period of 5 years following the end of the trial. Each investigator is responsible for ensuring records are retained and securely archived at site during the retention period and information supplied to the Chief Investigator. Where trial related information is documented in the medical records those records will be retained for at least 5 years after the last patient last visit. Access will be restricted to the sponsor and regulatory authorities.

Data from the study will be stored by the Central Office in accordance with the CTRU Archiving Standard Operating Procedure (SOP PM012) for 5 years following completion. Archived documents will be logged on a register which will also record items retrieved, by named individuals, from the archive. Electronic data will be stored in an 'archive' area of the secure CTRU server for a minimum of five years to ensure that access is future-proofed against changes in technology. Electronic data may also be stored (e.g. on a compact disc) with the paper files.

12. Data access and quality assurance

The sponsor will permit monitoring and audits by the relevant authorities, including the Research Ethics Committee. The investigator will also allow monitoring and audits by these bodies and the sponsor, and they will provide direct access to source data and documents in line with SOP QU001 and SOP DM009.

The study will use the CTRU's in-house data management system for the capture and storage of participant data. The system stores all data in a PostgreSQL database on virtual servers hosted by Corporate Information and Computing Services (CICS) at the University of Sheffield. Industry standard techniques are used to provide security, including password authentication and encryption using SSL/TLS. Access to the system is controlled by usernames and encrypted passwords, and a comprehensive privilege management feature is used to ensure that users have an appropriate level of access to data required to complete their tasks. This can be used to restrict access to personal identifiable data.

Participant confidentiality will be respected at all times. Patient/participant names and contact details will be collected and entered on the database. Access to these personal details will be restricted to users with appropriate privileges. All other data will be anonymised and will only be identifiable by participant ID number, and no patient identifiable data will be transferred from the database to the statistician. The CRF will collect demographic details.

The data management system provides validation and verification features which will be used to monitor study data quality, in line with CTRU SOPs and the DMMP. Error reports will be generated where data clarification is required.

13. Publication

Dissemination will be undertaken through peer reviewed scientific journals and clinical and academic conferences. We will also ensure regular dissemination to the advisory group and provide regular project bulletins to interested parties via the study website.

The study team are obliged, by the terms of its contract, to notify the HTA programme of any intention to publish the results of HTA-funded work at least 28 days in advance of publication in a journal. This also applies to public oral and poster presentations. The Trial Steering Committee will be also be notified of publications which report the final output of the study.

14. Finance

The trial has been financed by the NIHR HTA and details have been drawn up in a separate agreement.

15. Ethics approval

The trial will be submitted to a NHS Research Ethics Committee (REC) through the Integrated Research Application System (IRAS). The approval letter from the ethics committee and copy

of approved patient information leaflet, consent forms and CRF/ questionnaires will be sent to the CTRU before initiation of the study for each site and participant recruitment.

The trial will be submitted for NHS research governance approval for each recruitment site.

16. Regulatory approval

This trial will be submitted for NHS R&D approval by participating sites.

17. Indemnity / Compensation / Insurance

The University of Sheffield has in place insurance against liabilities for which it may be legally liable and this cover includes any such liabilities arising out of this research project.

18. References

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APPENDIX C: LITERATURE REVIEW SEARCH STRATEGIES

MEDLINE via Ovid search strategy

- 1 exp Stroke/ (97875)
- 2 stroke.mp. (205382)
- 3 1 or 2 (224664)
- 4 exp Rehabilitation/ (162746)
- 5 rehabilitation.mp. (132998)
- 6 therapy.mp. (1943519)
- 7 4 or 5 or 6 (2114992)
- 8 fidelity.mp. (17642)
- 9 treatment integrity.mp. (203)
- 10 treatment manual.mp. (180)
- 11 8 or 9 or 10 (17977)
- 12 3 and 7 and 11 (41)
- 13 Date limit 1996-2016 (36)

PsychINFO via Ovid search strategy

- 1 exp Cerebrovascular Accidents/ (16098)
- 2 stroke.mp. (25351)
- 3 1 or 2 (26802)
- 4 exp rehabilitation/ (64305)
- 5 therapy.mp. (335831)
- 6 4 or 5 (382056)
- 7 fidelity.mp. (6102)
- 8 treatment integrity.mp. (828)
- 9 treatment manual.mp. (744)
- 10 Treatment Duration/ (3525)

11 7 or 8 or 9 or 10 (11051)

12 3 and 6 and 11 (29)

CINAHL search strategy

1 (MH "Rehabilitation+")

2 "therapy"

3 S1 OR S2

4 "stroke"

5 "fidelity"

6 treatment integrity

7 implementation fidelity

8 treatment manual

9 "therapy protocol"

10 (MM "Patient Compliance")

11 S5 OR S6 OR S7 OR S8 OR S9 OR S10

12 S3 AND S4 AND S11

13 Limiters - Published Date: 19960101-20160207

APPENDIX D: ETHICAL APPROVAL LETTER FOR STUDY TWO



Downloaded: 01/08/2016

Approved: 22/01/2015

Madeleine Harrison

Registration number: 140107454 School of Health and Related Research

Programme: HARR41 Health and Related Research (PhD/Health & Related Res PT)

Dear Madeleine

PROJECT TITLE: StepByStep computer therapy approach: establishing the key components and methods of measurement

APPLICATION: Reference Number 002436

On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that on 22/01/2015 the above-named project was approved on ethics grounds, on the basis that you will adhere to the following documentation that you submitted for ethics review:

- University research ethics application form 002436 (dated 05/01/2015).
- Participant information sheet 004385 version 1 (05/01/2015).
- Participant information sheet 004386 version 1 (05/01/2015).
- Participant consent form 004387 version 1 (05/01/2015).
- Participant consent form 004388 version 1 (05/01/2015).

If during the course of the project you need to [deviate significantly from the above-approved documentation](#) please inform me since written approval will be required.

Yours sincerely

Jane Spooner Ethics Administrator
School of Health and Related Research

APPENDIX E: INTERVIEW PRO FORMA



Interview pro forma

Title of Research Project: *StepByStep computer therapy approach: establishing the key components and methods of measurement*

Participant Identification Number for this study: _____

1. Interview type:

- Individual interview
- Joint interview

2. Gender:

- Male
- Female

3. Age: _____

4. Final level of education:

- No qualifications
- GCSE/ O levels
- A levels
- Diploma/ certificate in higher education
- Vocational training
- Degree (e.g. BA or BSc)
- Higher degree (e.g. MA or PhD)
- Other: _____

5. What is your **ethnic** group?

WHITE

- British
- Irish

MIXED

- White and Black Caribbean
- White and Black African
- White and Asian

ASIAN OR ASIAN BRITISH

- Indian
- Pakistani
- Bangladeshi

BLACK OR BLACK BRITISH

- Caribbean
- African

CHINESE

- Chinese

OTHER ETHNIC GROUP

- Please specify: _____

6. What is your role in relation to the StepByStep approach?

- SLT using the StepByStep approach with their patients
- Person with aphasia who uses the StepByStep approach for their own rehabilitation
- Relative or informal carer of StepByStep user
- Volunteer supporting people with aphasia to use the StepByStep approach
- Designer
- Researcher
- Other: _____

7. How long have you used the StepByStep approach?

8. How regularly do you use the StepByStep approach?

9. Do you have any biases relating to the StepByStep approach to declare?

**APPENDIX F: ETHICAL APPROVAL LETTER FOR DATA COLLECTION RELATING TO
THE PROCESS EVALUATION AND QUANTITATIVE DATA ANALYSIS FOR UK SITES**



NRES Committee Yorkshire & The Humber - Leeds West

Room 001, Jarrow Business Centre

Rolling Mill Road

Jarrow Tyne and Wear

NE32 3DT

Tel: 0191 428 3444

04 August 2015

Ms Madeleine Harrison

Big CACTUS Research Assistant (Tuesday)

Stroke Association Postgraduate Research Fellow (Monday, Wednesday - Friday) School of
Health and Related Research (SchARR)

University of Sheffield

Room 1.07 The Innovation Centre 217 Portobello

Sheffield S1 4DP

Dear Ms Harrison

**Study title: Cost effectiveness of aphasia computer treatment versus
usual stimulation or attention control long term post stroke (Big CACTUS)**

REC reference: 13/YH/0377

Protocol number: R/134248

Amendment number: Substantial Amendment 3 Amendment date: 17 July 2015

IRAS project ID: 138568

The above amendment was reviewed by the Sub-Committee in correspondence.

Summary of amendment

This amendment was submitted to make adjustments to the intervention arm of the study, including using version 5, rather than 4.5, of the study software and using different documents to maintain and record fidelity of StepByStep set-up, along with other changes.

Additionally, details of how intervention fidelity would be evaluated were clarified. Additional questions to the participant diary had also been added.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

In light of the additional questions being asked to the participant, the Sub-Committee requested sight of the original questions being asked to the participant in order to assess the additional version.

You responded on 31 July to provide the original questions that were being asked of the participant.

The Sub-Committee was satisfied with this response.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Letter from Madeline Harrison]		17 July 2015
Non-validated questionnaire [Lead Therapist Intervention Quiz]	1	09 July 2015
Non-validated questionnaire [Participant Diary Extra Questions]	1	16 July 2015
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 3	17 July 2015
Other [cover Letter - Participant Diary with Extra Questions]	1	15 July 2015
Other [Working Alliance Inventory]	1	13 July 2015
Other [Negative Effects of the Computer therapy questionnaire]	2.0	04 March 2015
Participant consent form [Lead Therapist Consent Form]	1	06 July 2015
Participant consent form [Volunteer Assistant Consent Form]	1	06 July 2015
Participant information sheet (PIS) [Participant Information Sheet - Lead Therapist]	1	06 July 2015
Participant information sheet (PIS) [Participant Information Sheet - Volunteer Assistant]	1	06 July 2015

Research protocol or project proposal [Tracked Changes]	4.0	17 July 2015
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Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

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/>

13/YH/0377:	Please quote this number on all correspondence
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Yours sincerely pp



Mr Anthony Warnock-Smith Alternate Vice-Chair

E-mail: nrescommittee.yorkandhumber-leedswest@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Mrs Anna Leesley, Sheffield Teaching Hospitals Research Department

Dr Rebecca Palmer, University of Sheffield

APPENDIX G: ETHICAL APPROVAL LETTER FOR DATA COLLECTION RELATING TO THE PROCESS EVALUATION AND QUANTITATIVE DATA ANALYSIS FOR SCOTTISH SITES

**Scotland A Research Ethics
Committee**

Research Ethics Service
2nd Floor Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone: 0131 465 5680



Enquiries to: Manx Neill
Extension: 35680
Direct Line: 0131 465 5680
Email: manx.neill@nhslothian.scot.nhs.uk

27 August 2015

Dr Rebecca Palmer
University of Sheffield
107 Innovation Centre
217 Portobello
Sheffield
S1 4DP

Dear Dr Palmer,

Study title: Cost effectiveness of aphasia computer treatment versus usual stimulation or attention control long term post stroke (Big CACTUS)
REC reference: 14/SS/0023
Protocol number: R/134248
Amendment number: REC Reference AM07
Amendment date: 04 August 2015
IRAS project ID: 143451

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		04 August 2015
Notice of Substantial Amendment (non-CTIMP)		04 August 2015
Other [Working Alliance Inventory]	1.0	13 July 2015
Other [Lead therapist intervention quiz]	1.0	09 July 2015
Other [Diary (extra questions) cover letter]	1.0	15 July 2015
Participant consent form [volunteer assistant]	1.0	06 July 2015
Participant consent form [lead therapist]	1.0	06 July 2015
Participant information sheet (PIS) [lead therapist]	1.0	06 July 2015
Participant information sheet (PIS) [volunteer assistant]	1.0	06 July 2015
Research protocol or project proposal	4.0	17 July 2015
Sample diary card/patient card [extra questions]	1.0	16 July 2015

Chairman Dr Ian Zealley
Vice-Chairman Dr Colin Setby

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

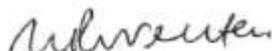
Statement of compliance

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.

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/>

14/SS/0023:	Please quote this number on all correspondence
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Yours sincerely,



Professor Nigel Webster
Chair

E-mail: manx.neill@nhslothian.scot.nhs.uk

Enclosures: *List of names and professions of members who took part in the review*

Scotland A REC

Attendance at Sub-Committee of the REC meeting

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Canon Matt McManus	Parish Priest	Yes	
Dr Rachel Smith	MRC Programme Manager (Training and Partnerships)	Yes	
Professor Nigel Webster	Chair of Anaesthesia & Intensive Care	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Dr Alex Bailey	Scientific Officer

APPENDIX H: STEPBYSTEP ACCESS FORM



StepByStep® access
[Intervention arm]

R /

Intervention start

Date participant given access to StepByStep
d d m m y y y y

Was there a delay of >2 weeks between randomisation and the participant being able to access the intervention?
 (if "Yes", please enter details below) Yes No

Details

Issues with access

Were there any periods during which the participant was unable to access the software?
 (if "Yes", please enter details in the table below) Yes No

Date access stopped	Date access resumed	Reason (e.g. hardware/software failure, health issues)
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End of Intervention

Will the participant retain access to StepByStep at the end of the intervention period (typically 6 months from randomisation)?
 e.g. home licence installed on patient's own computer Yes No

Date of key file export (at 6 months)
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Date of key file export (at 12 months)
d d m m y y y y

Date access removed
d d m m y y y y

APPENDIX J: ACTIVITY LOG: THERAPIST TIME WITH ASSISTANT(S)/VOLUNTEER(S)

R

Therapist time with assistant(s)/volunteer(s)

[intervention arm]



Lead therapist log of time spent with therapy assistants / volunteers in the intervention arm. Where the training/support relates to more than one participant, please record a line on each participant's log, dividing the time spent and distance travelled equally.

Date	Supporting...		Activity type(s) and duration (tick ✓ all that apply)					Mode of activity				Distance travelled (there and back) (if face-to-face)	Mode of transport (if face-to-face)	
	Therapy assistant(s)	Volunteer(s)	Providing training	Supporting assistant(s)/volunteer(s)	Providing technical support	Monitoring feedback form	Telephone	Email	Webcam	Face-to-face				
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APPENDIX K: DEVELOPMENT OF THE THERAPY PLANNING FORM

The need to record how the therapy was tailored by the therapists for each individual was recognised by the author prior to the start of recruitment of participants to the Big CACTUS trial. As such the Therapy Planning Form was designed by the author prior to conducting study two. Two aspects of study delivery subsequently identified by participants in study two as being important to measure can be measured via the data collected by the Therapy Planning Form: 1) what sequence of steps were selected and why (e.g. justification for tailoring), and 2) how the exercises were adapted in response to the PWA's performance. The benefit of deciding to collect this information prior to consulting key informants in study two was that the information was collected for all participants recruited to the trial, unlike measures of motivation and personalisation. The Therapy Planning Form had an additional use within trial to enable the trial monitor to determine the extent to which trial processes were being followed. This information was not fed back to participants.

The initial version of the Therapy Planning Form was developed based on the steps within the StepByStep software using the training slides developed by the research SLT working on the Big CACTUS trial in consultation with the software developers. The form had to be developed quickly due to the late arrival of the final version of the software (v5). The form was developed to reflect the choices made possible by the computer program to establish how clinicians have tailored the exercises on the StepByStep software. The form included boxes to write a justification of the therapist's choices in order to document the rationale for the choices made. The form was designed in discussion with the research SLT and the Big CACTUS study chief investigator. A specialist in data management was also consulted about the design and layout of the Therapy Planning Form which resulted in amendments to the formatting. In addition, an early version of the form was shown to a group of three therapists (September 2014) being trained on the project. The feedback they provided included:

- the need to add space to record any additional changes made following the initial set-up; and
- removing a justification box from the 'picture recognition' stage, unless the therapist has selected different options from those recommended in training.

The Therapy Planning Form was initially called the 'treatment fidelity monitoring form', but the name was perceived to have negative connotations and it was thought that the concept of 'fidelity' might not be understood by everyone. The final version of the Therapy Planning Form was sent to therapists prior to recruitment of the first participant to the trial.

APPENDIX L: THERAPY PLANNING FORM



R /

Therapy planning form

Intervention arm

To be completed by the lead therapist for all participants in the intervention arm whilst tailoring the StepByStep software.
Any changes made after the initial set up, by either the therapist or the volunteer/assistant, should be recorded on the final page.

Date of completion
d d m m y y y y



Summary of assessment results

Intervention arm

Please record a summary of the participant's assessment results from the naming test and from observations through general conversation

What types of error does the patient make?
(tick all that apply)

- Semantic paraphasias (chair → table)
- Phonemic paraphasias (brollie → broccoli)
- Sound substitutions, additions, omissions or transpositions (umbrella → umblerela)
- Neologisms (chair → wibble)
- Perseveration (saying a previous word again)
- Other.....

What seemed to help?
(tick all that apply)

- Whole word repetition
- Visual cues (seeing lips helped the patient to repeat)
- Whole written word
- A phonemic cue ('tel'... → television)
- A semantic cue ('you wear this on your head' → hat)
- A first letter cue (given by you or written/sky written by patient themselves)

Awareness

Is the patient aware of his/her errors?

Yes Partially No

Would encouragement to record and listen back to own errors be likely to help?

Yes No

Other important factors identified from assessment

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Therapy planning form

Intervention arm

Launch: step vs sequence



Which launch mode have you selected?

Step Sequence

If sequence, why?

Create alternatives



Have you created alternatives for any of the words/sentences?

Yes No

How many words have you created alternatives for?

How many sentences have you created alternatives for?

Detail the rationale for creating alternative words/sentences:

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Therapy planning form

Intervention arm

Picture recognition



Which settings have been selected?

Object display: Picture Word Sound

Option display: Picture Picture/word Word

Number of options: 2 3 4 6 8

Recommended settings:



If the recommended settings have **not** been selected please explain why:



TFF, Version 2.0, 05 Dec 2014



Therapy planning form

Intervention arm

Please do not feel limited by the number of copied steps detailed on each page. If you make more copies please make a note in the rationale section.

Confrontation naming



Has the step been copied? Yes No

How many times has the step been copied?

Circle chosen prompts for each 'confrontation naming' step, including standard and copied steps:

Steps	Prompts				
First confrontation naming step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word	
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition		
Second confrontation naming step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word	
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition		
Third confrontation naming step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word	
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition		

Detail the rationale for using the standard step only or for any changes/additions made:



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Therapy planning form

Intervention arm

Confrontation naming with feedback



Has the step been copied? Yes No

How many times has the step been copied?

Circle chosen prompts for each 'confrontation naming with feedback' step, including standard and copied steps:

Steps	Prompts				
First confrontation naming with feedback step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word	
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition		
Second confrontation naming with feedback step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word	
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition		
Third confrontation naming with feedback step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word	
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition		

Detail the rationale for using the standard step only or for any changes/additions made:



TFF, Version 2.0, 05 Dec 2014



Therapy planning form

Intervention arm

Using writing to cue naming



Has the step been copied? Yes No

How many times has the step been copied?

Circle chosen settings for each 'using writing to cue naming' step, including standard and copied steps:

Steps	Settings
First writing to cue naming step	Spelling type: Initial letter Copying Flash Anagram Whole word Prompts: <input type="radio"/> Voice recognition <input type="radio"/> Dictionary/button (written word) Keyboard: Easy Medium Full
Second writing to cue naming step	Spelling type: Initial letter Copying Flash Anagram Whole word Prompts: <input type="radio"/> Voice recognition <input type="radio"/> Dictionary/button (written word) Keyboard: Easy Medium Full
Third writing to cue naming step	Spelling type: Initial letter Copying Flash Anagram Whole word Prompts: <input type="radio"/> Voice recognition <input type="radio"/> Dictionary/button (written word) Keyboard: Easy Medium Full
Fourth writing to cue naming step	Spelling type: Initial letter Copying Flash Anagram Whole word Prompts: <input type="radio"/> Voice recognition <input type="radio"/> Dictionary/button (written word) Keyboard: Easy Medium Full
Fifth writing to cue naming step	Spelling type: Initial letter Copying Flash Anagram Whole word Prompts: <input type="radio"/> Voice recognition <input type="radio"/> Dictionary/button (written word) Keyboard: Easy Medium Full
Sixth writing to cue naming step	Spelling type: Initial letter Copying Flash Anagram Whole word Prompts: <input type="radio"/> Voice recognition <input type="radio"/> Dictionary/button (written word) Keyboard: Easy Medium Full



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Therapy planning form

Intervention arm

Using writing to cue naming (continued)



Detail the rationale for the spelling type selected (initial letter, copying, flash, anagram, whole word)

Detail the rationale for the presentation settings selected (keyboard type, capitals or keyboard keys)

Detail the rationale for the prompts selected (voice recognition, dictionary/button)



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Therapy planning form

Intervention arm

Please note the settings from the 'naming from grid' step will duplicate to the 'naming from memory' step and vice versa.

Naming from grid and Naming from memory



Number of pictures displayed? 4 6 8

Always show the same pictures? On Off

If 'off', number of attempts before 1 picture changes: 1 2 4

Detail the rationale for using the standard step only or for the changes made:



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Therapy planning form

Intervention arm

Using word in functional sentence (1)



Has the step been copied? Yes No

How many times has the step been copied?

Circle chosen prompts for each 'using word in functional sentence (1)' step, including standard and copied steps:

Steps	Prompts:			
First using word in functional sentences (1) step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition	<input type="checkbox"/> Hear and see written sentence
Second using word in functional sentences (1) step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition	<input type="checkbox"/> Hear and see written sentence
Third using word in functional sentences (1) step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition	<input type="checkbox"/> Hear and see written sentence

Detail the rationale for using the standard step only or for any changes/additions made.



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Therapy planning form

Intervention arm

Using word in functional sentence (2)



Has the step been copied? Yes No

How many times has the step been copied?

Circle chosen prompts for each 'using word in functional sentence (2)' step, including standard and copied steps:

Steps	Prompts			
First using word in functional sentences (2) step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition	<input type="checkbox"/> Hear and see written sentence
Second using word in functional sentences (2) step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition	<input type="checkbox"/> Hear and see written sentence
Third using word in functional sentences (2) step	<input type="checkbox"/> Semantic prompt	<input type="checkbox"/> First sound	<input type="checkbox"/> First letter	<input type="checkbox"/> Written word
	<input type="checkbox"/> Whole word	<input type="checkbox"/> Record & playback	<input type="checkbox"/> Voice recognition	<input type="checkbox"/> Hear and see written sentence

Detail the rationale for using the standard step only or for any changes/additions made.



TFF, version 2.0, 05 Oct 2014



Therapy planning form

Intervention arm

Please use this page to record changes made after initial set up

For example: reducing level of difficulty, adding more vocabulary

Date	Step name	Details and rationale for changes

APPENDIX M: DISCUSSION OF THE RELIABILITY OF FREQUENCY AND DURATION DATA RECORDED BY THE STEPBYSTEP KEY FILE

Previous versions of the StepByStep software did not accurately record usage data because it would carry on recording practice sessions indefinitely. One of the intervention designers was questioned about this during the initial study two interviews. In response, he explained that this inaccuracy had been rectified as a new function had been added to StepByStep v5.

“It’s looking for a difference between the last result and the end of the, well it’s a particular result that it’s looking at and the end of the session. So if you imagine that someone’s going through a naming exercise and they’ve got five items in the naming exercise and they leave the last one, they just leave it on and don’t exit and they exit later on it checks between the last result and the exit time to see if it’s greater than 5 minutes then it brings the exit time back to the time of the last result.” S07 Designer and evaluator

Based on the information provided by the designers we would expect that the version 5 key files would provide more accurate recording of practice time than previous versions and this appeared to be the case in brief testing by the Big CACTUS trial team (e.g. therapy exercise left inactive mid-way through an exercise and inactive time was not recorded on five occasions). This was further supported by the comments of a patient participant in the study three interviews who described how they attempted to trick the computer software into recording more practice time than he actually did, but despite his best efforts it would only record active practice time.

“If it [the calendar] comes down and it’s got like a yellow thing that’s no good, that’s about twenty minutes or so, that’s no good I’ve got to get a green. So you’ve got to be at least half an hour, maybe a little bit over the top for it to actually transmit. And you can’t take any-, in my experience you can’t take well we’ve done three or four and then we’ll stop and read the paper cause it kicks out.[...] There’s loads of ways round it, take it from me I’ve tried most of them. So you’ve gotta do a full thirty minutes.” R11/03 high adhering participant

Both the quotes and the research teams testing indicate that StepByStep v5 does not record inactivity as practice time, moreover the quotes suggest the practice time recorded may be a conservative estimate as it does not record the time spent on the last item the participant attempted.

APPENDIX N: ACTIVITY LOG: THERAPY ASSISTANT/ VOLUNTEER TIME WITH PARTICIPANT

R

Therapy assistant / volunteer time with participant [intervention arm]



To be completed using information on the "Feedback form (for volunteers or therapy assistants)"*

Date of home visit	Therapy assistant/volunteer initials	Designation*	Distance travelled (there and back)	Mode of transport†	Activity type(s) and duration (tick ✓ all that apply)				Other contact(s) since last visit (tick ✓ all that apply)				Total distance travelled (if face-to-face)	
					Setting up/adjusting computer or microphone	Encouraging/modelling use of the computer therapy	Assistance with using software	Conversations to practise using the words	Email	Telephone	Video call	Face-to-face		
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APPENDIX O: DEVELOPMENT OF THE LEAD THERAPIST QUIZ

The lead therapist quiz was designed to be completed by any of the therapists taking on the lead therapist role. Lead therapist refers to their role in setting up the therapy on the StepByStep software. Typically the lead therapist was also the principal investigator (PI) at site. The quiz questions were written by four members of the Big CACTUS team who were responsible for designing and delivering the two day training session to the PIs and lead therapists. Each member was responsible for delivering different aspects of the training to reflect their areas of expertise. As such the task of writing the questions and answers for the quiz was divided so the person who delivered each section of training was asked to write questions and answers about that section. They were asked to write one or two question per training section of which there were 22 in total. 27 questions were included in the quiz of which 11 were about the intervention and 16 were about the trial.

The full version of the quiz was only sent out on the first occasion. Therapists were given feedback on their answers to the first 16 trial related questions to ensure that trial practices were being carried out per protocol at all 20 sites. No feedback was provided on the 11 questions about the intervention because it was a pragmatic trial (testing the intervention in the real world) and therapists would not normally get feedback to improve their understanding and delivery of the intervention. In subsequent versions of the quiz, sent out at 10 and 15 months post-randomisation of the first participant, the therapists were only asked to complete the questions about the intervention.

Once the quiz questions had been compiled it was piloted with a SLT who had attended the full PI training, but was not going to be taking on either the lead therapist or PI role. The SLT was asked to complete the quiz (to check the questions elicit the sort of answers we would expect), and provide feedback on whether any of the questions were unclear or need re-wording. The feedback related to the wordiness of some of the questions, the use of abbreviations and concepts that needed more clarification. Changes were made in line with the suggestions.

In the second phase of piloting one of our PIs who attended the first training session was asked to complete the draft quiz as an internal pilot. The feedback was summarised by the lead therapist in an email and is included here:

“Completing it felt somewhat stressful, something to do with being 'put on the spot' as it were. I have not had a participant randomised to computer treatment arm since December, so felt rather rusty with regards to the StepByStep section. My usual practice is to read through the relevant BC training sections prior to visits, to refresh my memory. The questions were clear and had a 'good flow', although I was not sure about section1 Q11: did

you mean what or who? It would be useful to know more about the purpose of the questionnaire.”

As a result of the feedback and the lead therapists responses to the questions, some minor changes were made to the wording and more information was added about the purpose of the quiz. The additional information about the purpose of the quiz might also serve to reduce the feeling of being ‘put on the spot’. Since no major changes followed the internal pilot the score for the internal pilot was used and the PI was not asked to complete the amended test.

APPENDIX P: LEAD THERAPIST QUIZ

Participant Identification Number:

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Big CACTUS lead therapist intervention quiz

Please complete the questions below without consulting your slides/notes from training, any other trial documentation or your previously completed version of the quiz. The purpose of the quiz is to look at how your knowledge about the StepByStep© approach changes over the time. We will not provide any feedback because we do not want to influence how the intervention is provided after training (as this would not reflect usual clinical practice). Please complete the quiz within the next two weeks and return in the pre-paid envelope provided.

Q1. What are the three key elements of the StepByStep approach to aphasia therapy?

- 1.
- 2.
- 3.

Q2. Give two reasons why the treatment is tailored to the individual?

- 1.
- 2.

Q3. Who selects the vocabulary for the participant to practise and what strategies can be used to do this?

Q4. Which two searching views can you toggle between to look for vocabulary?

Q5. What information should you collect to decide how StepByStep should be tailored?

Q6. What document should you complete before tailoring the steps?

Q7. What do you need to consider adding for new vocabulary items if a participant is in the computer therapy arm?

Q8. How often should you and the volunteer/assistant recommend the participant to practice?

Q9. How often and for how long should the volunteer/assistant visit the participant?

Q10. In what circumstances should the volunteer/assistant direct a participant to a more appropriate level of difficulty?

Q11. What would you advise the volunteer/assistant to do if they fed back to you that the participant insists on keeping on practicing the easier levels because they can get them all correct?

Date of completion (dd/mm/yyyy): _____

APPENDIX Q: DEVELOPMENT OF MEASURES OF PARTICIPANT RESPONSIVENESS

Which components to measure?

Of the ten components selected as being important to measures in order to explore the process of delivering and receiving the StepByStep approach to aphasia therapy, three components related to participant responsiveness were selected:

Patient motivation/buy-in

Ease of use of the software

How much have the words/photos been personalised

How to measure components?

How to measure the components of the intervention was discussed during the qualitative interviews with key informants. It is important to bear in mind that the key informants were asked this question because they were knowledgeable about the intervention, not research methods, as such the measures recommended by key informants have not necessarily been selected, but they did help the author to explore different methods that might be applicable.

Patient motivation/buy-in: the amount people practiced was seen by some participants as a proxy for motivation, however as one participant recognised, some people practice because they have a very motivated carer rather than because they are motivated themselves. Thus demonstrating that adherence to intensive practice is not necessarily an accurate measure of an individual's motivation to practice.

Ease of use of the software: suggestions for how the ease of use of the software could be measured included counting how many times people asked for help and directly asking the participants.

How much have the words/photos been personalised: a similar response was provided by multiple participants who suggested that you could look at the number of new words added, as opposed to those selected from the existing library of words pre-populated with images, prompts and cues, because the new words added will always be personal. However, the author and some of the participants were aware that this was not a valid measure of personalisation because the items selected from the library could still be personal to that individual (e.g. if they want to practice the word Tesco because that is where they shop Tesco is pre-programmed into the software, so it does not need to be added).

As a result of the apparent validity issues with the proxy measures suggested by participants in study two it was decided that self-report measures would be used to measure participant responsiveness.

How to design the measures?

Advice on designing the self-report measures was sought from the Big CACTUS study patient advisory group to ensure the questions and supporting pictures would convey the intended meaning to as many participants as possible. The author met individually with two patients with aphasia and one of their carers. The author created two different examples of how the questions could be worded, using different pictures and different scales. The examples followed accessible design principles, including: large font, lots of white space, pictures to display concepts, etc.

Recommendations from a PWA (TM) and their carer (IM):

- *Front page:* IM suggested adding the Big CACTUS logo and putting emboldened words in green for emphasis.
- *Comparison of scales (COAST type boxes with five written statements versus 1-10):* the preferred option for the motivation and ease of use question was a scale from 1-10 with the words 'not motivated' and 'very motivated' added and 'very easy' and 'not easy at all' added at each end of the scale. For the last question about relevance of the vocabulary IM thought neither scale was appropriate and instead suggested a 5 point scale from 'All' to 'None' should be used with enough space for the word to be circled.
- *Motivation question:* they both preferred the pictures of the men as they were clearer and less confusing. IM pointed out that the pictures of the women were busier and had lots of other things in the photo.
- *Ease of use question:* IM preferred the question 'how easy is it to use the StepByStep software?' compared to 'did you know what to do with the computer therapy?'. TM preferred the pictures of the women than the men. IM suggested adding speech bubbles with a question mark and thumbs up to make the pictures clearer.
- *Personally relevant vocabulary question:* IM preferred the question 'are the words on the StepByStep computer therapy words you want to say?' compared to 'are the words on the computer relevant to what you want to say?'. We had a lot of discussion about the pictures the IM in particular felt that the pictures were not useful.

Recommendations from a PWA (CW):

For this meeting I had three versions of the questions: the two initial drafts and a version amended following all of the recommendations suggested by TM and IM.

- *Invitation letter from participant diary:* CW thought adding a sentence to the invitation letter from the participant diary was a good idea, but suggested it should be in green to make it stand out to people reading it as new information.
- *Comparison of scales (COAST type boxes with five written statements versus 1-10):* CW agreed with the previous recommendations about using the 1-10 scale for the first two questions and the 5 point scale from 'All' to 'None' for the third question. CW suggested that the key for the scale should be emboldened so it is more obvious (e.g. not motivated).
- *Motivation question:* CW also preferred the pictures of the men.
- *Ease of use question:* CW also preferred the pictures of the women, but suggested that the woman showing 'not easy to use' looked "sad and a bit poorly" (this supported the fact that TM was very clear she was not like that woman when she tried to answer the question previously) and CW thought it would be better if it was the same woman in both pictures. A picture of the same woman as the 'easy to use' image was found and added.
- *Personally relevant vocabulary question:* CW thought it was preferable to have a picture rather than not, but suggested using picture from the StepByStep computer program on the computer screen and rather than a line drawing.
- *Additional comment:* CW thought back to when she first had her stroke and said that she would have matched the picture on the left to 1 and the picture on the right to 10 because she would not have understood that she was being asked how she felt as she would not have been able to read and understand the word 'you'. CW suggested adding an example page, but that had issues again in how to show 'you' is 'you' without language. Further discussion of this point with the chief investigator led to the conclusion that people need to have a certain level of written understanding in order to comprehend the questions.

Who should complete the measures?

When working with an aphasic population, sending a questionnaire by post is not straightforward due to impairments in written comprehension and expression. As such, after the discussion with CW from the patient advisory group, the chief investigator of the Big CACTUS study and two speech and language therapists it was decided that the questions should only be sent to participants who were known to have written comprehension at the

three key word level based on the score from the Consent Support Tool (Jayes & Palmer, 2014) or participants who also have a carer involved in the trial who would be able to answer the questions in discussion with the participant or on their behalf. A box has been added so that we will know when the form has been completed by a carer. It will therefore be possible to determine whether there is a difference between those forms completed by the participant and those completed by a carer.

APPENDIX R: MEASURES OF PARTICIPANT RESPONSIVENESS



Questions about the computer therapy

We want to find out how you feel about the computer therapy.

On each page, please **circle** the **number** or **word** that best describes your **feelings** about the **computer therapy today**.

Please return this form in the prepaid envelope provided.

If you are a **relative** or **carer** completing the form on behalf of the participant please, **tick** this box:

Participant diary extra questions, version 1.0, 16 July 2015

How **motivated** are you to **practise** your **StepByStep** computer therapy exercises?




1
Very motivated

2

3

4

5

6

7

8

9


10
Not motivated

Participant diary extra questions, version 1.0, 16 July 2015

How **easy** is it to use the **StepByStep** computer therapy?



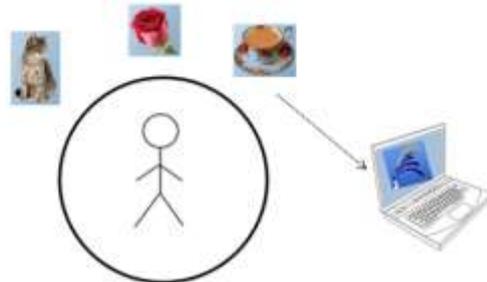
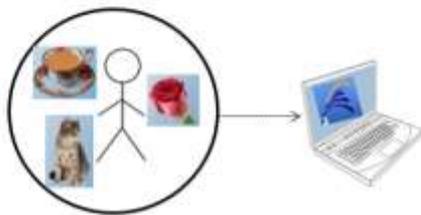
1 2 3 4 5 6 7 8 9 10

Very easy

Not easy
at all

Participant diary extra questions, version 1.0, 18 July 2015

Are the words on the StepByStep computer therapy **words you want to say**?



All

Most

Some

A few

None

Participant diary extra questions, version 1.0, 18 July 2015

APPENDIX S: ADDITIONAL CARER DATA FOR STUDY FOUR



Additional carer data

Title of Research Project: *Adherence to computer aphasia therapy: who can manage intensive practice?*

Participant Identification Number: _____

1. Interview type:

- Individual interview
- Joint interview

2. Gender:

- Male
- Female

3. Relationship to person with aphasia: _____

4. Date of birth: _____

APPENDIX T: INTERVIEW SCHEDULE FOR QUALITATIVE INTERVIEWS IN STUDY FOUR

Adherence to computer aphasia therapy

Interview schedule

1. How much does your communication problem affect your life? *[scale: not very much to a lot]*
 - Can you tell me about how your communication problem affects your life?
 - When did your communication problem start?
 - Has it got worse, better or stayed the same?
2. How important is it to you that your communication problem improves? *[scale: not very important to very important]*
 - How important was speech to you before you had your stroke?
 - Do you think your communication has the potential to get better?
3. How much speech therapy have you had before? *[scale: not very much to a lot]*
 - Can you tell me about the speech therapy you have had before?
 - Did it work for you? How?
4. When [therapist name] told you about the computer therapy, what were your first thoughts? *[show some pictures to choose from]*
 - Did you think you would be able to use the computer therapy before you started using it? How come?
 - What did you expect from doing the computer therapy?
5. When did you start using the computer therapy? When did you finish? *[show calendar]*
 - *[If different to what we would expect, ask why?]*
6. How many times a week did you practise? *[show weekly calendar]*
 - What made you practise more? *[show some pictures to choose from]*
 - What made you practise less? *[show some pictures to choose from]*

- When did you practise?
 - How did you decide when to practise?
 - Did the amount you practised change over time?
7. How long did each practice session last? *[show a clock or time options]*
- What made you practise longer? *[show some pictures to choose from]*
 - What made you practise for less time? *[show some pictures to choose from]*
8. How often and for how long did [therapist name] and [volunteer name] suggest you should practise?
9. Can you tell me about using the computer therapy?
- What was good? What was bad?
 - What was easy? What was hard?
10. How often did you see [volunteer name] and how long for? *[show calendar and clock]*
- *[If different to what we would expect, ask why?]*
 - What did you do during the visits?
 - Can you tell me about your relationship with [volunteer name]?
11. How often did you see [therapist name] and how long for? *[show picture of therapist and calendar and clock]*
- Can you tell me about your relationship with [therapist name]?
 - How did [therapist name and volunteer name] feel about the computer therapy?
12. Did anyone else help you with the computer therapy?
- What help did they provide?

APPENDIX U: SELECTED PAGES (THOSE WITH IMAGES INCLUDED) FROM THE MATERIALS TO SUPPORT PWA TO PARTICIPATE IN QUALITATIVE INTERVIEWS IN

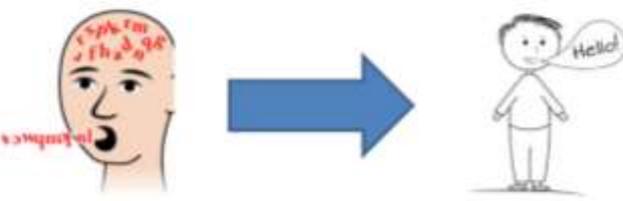
1. How much does your **communication problem** affect your **life**?



STUDY FOUR

2. How **important** is it to you that your **communication problem improves**?



not important **very important**

3. How much **speech therapy** have you had **before**?



5. When did you **start** using the **computer therapy**? When did you **finish**?

	January
2014	February
	March
2015	April
	May
2016	June
	July
	August
	September
	October
	November
	December

6. How many **times** a **week** did you **practise**?

1 2 3 4 5 6 7

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

7. How **long** did **each** practice **session** last?



8. How **often** and for how **long** did your **therapist** and your volunteer or therapy assistant suggest you should **practise**?

1 2 3 4 5 6 7 times per week



10. How **often** did you see your **volunteer** or **therapy assistant** and **how long** for?

1 2 3 4 5 6 7 times per month



APPENDIX V: INTERVIEW SCHEDULE FOR CARER INTERVIEWS IN STUDY FOUR

Adherence to computer aphasia therapy

Interview schedule for carers

[Replace X with patient participant's name. If a comprehensive answer has been obtained from the patient participant it may be appropriate to skip some questions.]

1. Can you tell me about how X's communication problems affect their life?
 - When did their communication problem start?
 - Has it got worse, better or stayed the same?

2. How important is it to X that their communication problem improves?
 - How important was speech to X before he/she had the stroke?
 - Does X think their communication has the potential to get better?

3. How much speech therapy has X had before?
 - Can you tell me about the speech therapy X had before?
 - Did it work for X? How?

4. When [therapist name] told X about the computer therapy, what were X's first thoughts?
 - Did X think he/she would be able to use the computer therapy before he/she started using it? How come?
 - What did X expect from doing the computer therapy?

5. When did X start using the computer therapy? When did X finish?
 - [If different to what we would expect, ask why?]

6. How many times a week did X practise?
 - What made X practise more?
 - What made X practise less?
 - When did X practise?
 - How did X decide when to practise?
 - Did the amount X practised change over time?

7. How long did each practice session last?
 - What made X practise longer?
 - What made X practise for less time?

8. How often and for how long did [therapist name] and [volunteer name] suggest X should practise?

9. Can you tell me about X using the computer therapy?
 - What did X find good? What did X find bad?
 - What did X find easy? What did X find hard?

10. How often did X see [volunteer name] and how long for?
 - [If different to what we would expect, ask why?]
 - What happened during the visits?
 - Can you tell me about X's relationship with [volunteer name]?

11. How often did X see [therapist name] and how long for?
 - Can you tell me about X's relationship with [therapist name]?
 - How did [therapist name and volunteer name] feel about the computer therapy?

12. Did anyone else help you with the computer therapy?
 - What help did they provide?

13. How did X using the computer therapy impact on you?

APPENDIX W: NOTES FROM BIG CACTUS PATIENT AND CARER ADVISORY GROUP MEETING STUDY FOUR

Notes from Big CACTUS advisory group meeting

12th May 2016, 11.00 – 13.00



Choosing pictures to support interview questions

Feedback from the PPI group in response to each question/picture:

1. How much does your **communication problem affect** your **life**?

- Don't include any "life" pictures – just the two people in the middle
- Can have cue cards for "life" activities to stick down as prompts if needed
- Ian & Chris liked the scale but Tim interpreted the '++' meaning everything to be fine
- Use smiley face/unhappy face scale instead and remove the words as the annotation is distracting

2. How important is it to you that your **communication problem improves**?

- Use a smiley face/unhappy face scale again for consistency and remove the words
- Make sure the word 'important' is in **bold**
- A third picture with a whole sentence in a speech bubble isn't required, stick with two

3. How much **speech therapy** have you had **before**?

- The question is easier to understand as it is much shorter
- This question could do with some visual prompting with hands far apart to indicate 'a lot' or hands close together to indicate 'a little bit' or 'not very much'
- Use a smiley face/unhappy face scale again for consistency and remove the words
- The map in the picture could cause confusion

4. When your therapist told you about the **computer therapy**, what were your **first thoughts**?

- Traudel was keen in the first instance, despite not having experience with computers. Required shorter sessions though otherwise would get frustrated.
- Tim thought it was rubbish at first but as soon as practised more started to think 'I can do it' and became more motivated when started getting things right
- Ian commented that if the carer isn't computer literate either, they could both feel overwhelmed

- The group thought pictures weren't necessary for this question, just prompting from the interviewer if necessary

5. When did you start using the computer therapy? When did you finish?

- The group commented that the calendar was too small and it only showed 2016, not 2015
- The group suggested to list months instead so participants can choose a year and then choose a month
- 'Start' 'computer therapy' and 'finish' should be **bold** in the question

6. How many times a **week** did you **practise**?

- The table shown could be useful for those who had a weekly routine and practised on the same days each week
- Include a list of 1 – 7 above this table so participants have the choice of choosing a number of days or pointing to the days they practised in the table (can cover up either option if needed)
- When asking the question, interviewer should say 'usually' instead of 'on average'

7. What made you practise more?

- Motivation
- Success
- Results – seeing their progress
- Having help
- Therapist & feedback or knowing your therapist is due to visit soon
- Having something to aim for
- Coming to the end of the study
- Having software set up
- Familiarity with a tablet or a laptop
- **Bold** 'practise more'

8. What made you practise less?

- If not 100%
- Tired
- Frustrated or overwhelmed – do shorter sessions
- Not feeling comfortable with the software
- Lazy
- Other commitments
- Software glitches
- If no one is there for support
- **Bold** 'practise less'

9. How long did each practice session last?

- Plain clock is too ambiguous for some. Could use the clocks used on the agenda indicating 15 min, 30 min etc.

- **Bold** 'how long' and 'practise'

10. What made you practise longer?

- If you were better could practise for longer. If not as good, wouldn't practise as much
- If not got 100% or improved on last mark
- If it takes longer to understand
- **Bold** 'practise longer'

11. What made you practise for less time?

- If going out or tea is ready (busy)
- Not 100%
- Tired
- Disinterested
- If it's hard work / not computer literate

APPENDIX X: ETHICAL APPROVAL FOR QUALITATIVE DATA COLLECTION FOR STUDY FOUR



Downloaded : 05/05/2016

Approved : 18/04/2016

Madeleine Harrison
Registration number: 140107454
School of Health and Related Research
Programme: HARR41 Health and Related Research (Phd PT)

Dear Madeleine

PROJECT TITLE: Adherence to computer aphasia therapy: who can manage intensive practice?
APPLICATION: Reference Number 008063

On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that on 18/04/2016 the above-named project was **approved** on ethics grounds, on the basis that you will adhere to the following documentation that you submitted for ethics review:

- University research ethics application form 008063 (dated 01/04/2016).
- Participant information sheet 1016859 version 1 (01/04/2016).
- Participant information sheet 1016862 version 1 (01/04/2016).
- Participant information sheet 1016861 version 1 (01/04/2016).
- Participant information sheet 1016860 version 1 (01/04/2016).
- Participant information sheet 1016858 version 1 (01/04/2016).
- Participant consent form 1016863 version 1 (01/04/2016).
- Participant consent form 1016849 version 1 (01/04/2016).

The following optional amendments were suggested:

â€¢ Information Sheet: Section 5 â€” rephrase â€” any benefitsâ€™ to â€”treatmentâ€™ to avoid confusion. â€¢ Consent form: Consider whether oral consent could be recorded instead or in addition to forms. â€¢ Information Sheet: Ensure states findings may be used for future research.

If during the course of the project you need to [deviate significantly from the above-approved documentation](#) please inform me since written approval will be required.

Yours sincerely

Ellen Nicolson
Ethics Administrator
School of Health and Related Research

