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School of Health Sciences
Division of Language and Communication Science

**Investigation of different therapy approaches for
aphasia in the Greek language**

Evangelia – Antonia Efstratiadou

**Thesis submitted is presented for the Degree of
Doctor of Philosophy
of
City University of London**

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Abstract

Background and aims: This PhD is part of the Thales Aphasia project. The Thales Aphasia project aimed to provide an in-depth exploration of neuropsychological and linguistic deficits in Greek speaking people with aphasia and to investigate the efficacy of speech and language therapy interventions. Two interventions were evaluated: mapping therapy and Elaborated Semantic Feature Analysis (ESFA). This thesis reports on the efficacy of ESFA. ESFA is a modified version of Semantic Feature Analysis (SFA), which prompts the participant to elaborate the features described into a sentence. Two different aims are investigated: (a) the efficacy of Elaborated Semantic Features Analysis (ESFA) therapy versus no therapy (b) the relative efficacy of two different approaches of delivering therapy – direct (individual therapy) versus combination therapy (individual together with group therapy) and the relative impact of each therapy approach on a range of outcome measures tapping different WHO ICF domains.

Methods: The study is a randomised trial using a waiting list control. Of the 72 participants of Thales, 58 met the eligibility criteria for speech and language therapy and 39 were allocated to ESFA (19 allocated to mapping therapy). Participants were randomised via recruitment order to one of three groups- two groups of therapy (direct or combination) and the waiting list control group. Of the 38 that had ESFA, 12 were randomised to the waiting list control group and 26 to one of the two ESFA therapy approaches. Participants on the therapy approaches were assessed two times before therapy (double baseline, week 1- 6), post-therapy (week 19), and 3-months later (follow-up). Participants on the waiting list control were assessed three times before therapy (week 1-6-19) and then were randomly allocated to one of the two approaches for ESFA treatment and were reassessed after the 12-week treatment (post-therapy) and 3 months later (follow-up). Both therapy groups had equal intensity and dosage- three hours of ESFA per week for 12 weeks (36 hours): those that received direct ESFA had three 1-hour sessions per week; those that received combination ESFA had one 90-minute session of group ESFA and two 45-minute sessions of individual ESFA per week. The primary outcome measure was confrontation naming of the 260 colourised pictures initially

developed by Snodgrass and Vanderwart (1980) (Rossion & Pourtois, 2004). Secondary outcome measures included a range of assessments tapping on all WHO ICF levels: Boston Naming Test (BNT), Discourse Measurement with Cookie Theft picture, Functional Assessment of Communication Skills for adults (ASHA – FACS), Stroke and Aphasia Quality of Life scale (SAQOL-39g), General Health Questionnaire (GHQ-12) and EQ-5D.

Therapy materials appropriate to each person were chosen at baseline before initiation of therapy. At baseline, each participant had to name the 260 pictures. The pictures were randomly presented to each participant for naming across three trials without any cuing or feedback. Based on the results of these trials, the pictures that participants failed to name on at least two trials were selected as potential treatment materials. This process of stimulus selection resulted in a set of treatment and probe items that were individual to each participant.

To test (a) the efficacy of ESFA therapy (n=26) versus no therapy (n=12) mixed within-between ANOVAs were used with group as the between variable (2 groups: ESFA versus control) and time as the within variable (3 levels: weeks 1, 6, 19). To test (b) the relative efficacy of direct (n=22) versus combination (n=14) ESFA, mixed within-between ANOVAs were used with group as the between variable (2 groups: direct versus combination ESFA) and time as the within variable (4 levels: two baselines, post-therapy and follow-up).

Results: After applying a Bonferroni correction for multiple comparisons, for (a) therapy versus control, there was a significant main effect of time on the primary outcome measure Greenhouse-Geisser $F(1.1, 39.38) = 26.04, p < .001$ with a large effect size ($\eta^2_p = .42$), and a significant interaction effect Greenhouse-Geisser $F(1.1, 39.38) = 9.56, p = .003$ with a large effect size ($\eta^2_p = .21$); whereby the therapy group improved significantly more from pre-therapy (week 6) [mean (SD) = 61.96 (49.40)] to post-therapy (week 19) [mean (SD) = 104.38 (73.91)] than the control group [week 6 mean (SD) = 74.33 (62.94), week 19 mean (SD) = 81.83 (69.90)]. There was a significant main effect of time for the BNT ($p = .002$) with a large effect size ($\eta^2_p = .19$), with the significant difference between

the firsts two baselines and BL3/post therapy. There was an interaction effect, which did not remain significant after adjusting for multiple comparisons, for the SAQOL-39g psychosocial domain ($p = .013$) ($\eta^2_p = .12$) and the overall SAQOL-39g score ($p = .015$) ($\eta^2_p = .11$), with the therapy group improving with therapy, and the control group not improving.

For (b) direct versus combination ESFA, there was a significant main effect of time on the primary outcome measure for both approaches, Greenhouse-Geisser $F(1.89, 64.53) = 32.95$, $p < 0.001$ with large effect size ($\eta^2_p = .49$). Pairwise comparisons showed there was a significant difference between the two baselines (mean difference = 10.23, $p = .003$), a significant difference between both the baselines and post-therapy (mean differences = 49.70 and 39.45, $ps < .001$) and a significant difference between both the baselines and follow-up (mean differences = 43.45 and 33.22, $ps < .001$). The post therapy gains were maintained, i.e. there was no significant drop from post-therapy to follow up. There was also a significant main effect of time with large effect size for the BNT ($p < .001$) ($\eta^2_p = .29$), with significant differences in pairwise comparisons between both baselines and post therapy and both baselines and follow-up; and the ASHA-FACS ($p = .001$) ($\eta^2_p = .18$), with significant differences between both baselines and the follow-up assessment. The interaction and group effects were not significant.

Conclusion: This PhD is the first to explore the efficacy of ESFA in a randomised group design. Results supported the efficacy of ESFA therapy versus no therapy. ESFA therapy led to gains in naming, communication and quality of life for people with aphasia. Gains were similar in the two therapy approaches and were maintained over a three-month follow-up. Pending further research to confirm the reliability of the results and allow meaningful effects to be detected on a range of outcome measures, ESFA may be a useful therapy to adopt in practice.

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Setting the scene

The present PhD study ran within the framework of the Thales Aphasia project and was nested in the Thales speech and language therapy group. The first and second supervisors, Professor Hilari and Dr. Papathanasiou, were principal co-investigators of the speech and language therapy group, and the PhD candidate, Eva Efstratiadou, was a research assistant on Thales Aphasia project.

Thales Aphasia Project

The Thales Aphasia project (<http://thales-aphasia.phil.uoa.gr/general-objectives.html>) was a three years and nine months' project, funded by the European Union. This project commenced in January 2012 and ran in Greece, in the prefectures of Attica and Achaia. To date, it is the largest investigation of aphasia in Greek. The project was based in the Department of Linguistics of the School of Philosophy of the National and Kapodistrian University of Athens. The Chief Investigator of the Thales project was Professor Spyridoula Varlokosta.

The objectives of the Thales project were the following: a) an in-depth investigation of different linguistic levels in aphasia and of their interrelations b) a study of the relationship between aphasia and other neuropsychological disorders c) an evaluation of aphasic disorders, their symptoms and level of severity, in relation to the location and extent of left-hemisphere damage, and d) an in-depth investigation of the efficacy of different types of intervention in aphasia.

The Thales project was carried out by a multidisciplinary team of linguists, neurolinguists, neuropsychologists, cognitive scientists, neurologists and speech and language therapists, organised into three groups: the neurolinguistics group, the neuropsychology group and the speech and language therapy group.

The neurolinguistics group investigated morphological and syntactic phenomena and narratives in people with aphasia. The objective of this group was to associate the different levels of the “microstructure” of language (i.e. morphology, syntax and

sentence-level) with the “macrostructure” (i.e. communicative ability and discourse. The study of microstructure employed structured tasks to examine different levels of linguistic analysis (i.e. morphology and syntax). The examination of the macrostructure was achieved through analysis of spontaneous language and narrative production. The group consisted of eleven researchers, coordinated by Dr. Spyridoula Varlokosta (Professor of Psycholinguistics, Department of Linguistics, Faculty of Philology, University of Athens).

The Neuropsychology Group investigated the relationship between aphasia and performance on tasks tapping into different cognitive functions, the different sources of variability in the performance of speakers with aphasia, as a function of their processing ability, the resource demands of the tasks, as well as the interrelations among neuropsychological and language functions over the natural course of aphasia. The group consisted of seven researchers, coordinated by Dr. Alexandra Economou (Assistant Professor, Department of Psychology, University of Athens).

The Speech and Language Therapy Group investigated the efficacy of speech and language therapy at word and sentence level, delivered through different approaches. It also examined the relative impact of each therapy approach on outcomes, tapping on World Health Organization’s International Classification of Functioning, Disability and Health (WHO ICF) framework levels (ICF, WHO, 2001a), including quality of life. The group consisted of seven researchers, coordinated by Dr. Ilias Papathanasiou (Associate Professor, Department of Speech & Language Therapy, Technological Educational Institute of Western Greece).

Aims of the Original Thales Speech and Language Therapy Group

The Speech and Language Therapy group investigated the efficacy of two different therapy types: word level therapy and sentence level therapy.

Word level therapy focused on improving the ability of recalling words, by developing a list of semantic features related to a specific concept. This process was based on the principles of Semantic Feature Analysis (SFA). Semantic feature analysis is considered to improve retrieval of conceptual information by accessing semantic networks (Boyle & Coelho, 1995; Coelho et al, 2000; Boyle, 2004). Based on the SFA approach, the present study applied the Elaborated Semantic Feature Analysis (ESFA) therapy approach, which allows the participant to elaborate the features described, into a sentence (Papathanasiou & Michou, 2006). The intervention taps into isolated words, which are then used into a sentence. The purpose of ESFA is to enable the participant not only to recall a word, but also to facilitate transfer to connected speech.

Sentence level therapy focused on the principles of mapping therapy (Nickels, Byng & Black, 1991). Mapping therapy delineates the meaning relationships of a sentence's constituents and expresses these relationships through the surface form, particularly in terms of word order (Marshall, 2013). The intervention required the person to think about the roles in any event being described and where these roles are positioned in the sentence (Marshall, 2013).

Individuals with aphasia were recruited from private and state hospitals in Greece. They were assessed and, depending on their performance on screening measures, they were allocated to either sentence or word level therapy. It was then planned that participants would be randomly allocated to one of the following three therapy approaches: direct –individual therapy; indirect – group therapy; and combination – individual and group therapy. The therapy regime was a 12-week speech and language therapy programme, comprising 36 hours of therapy. Outcome measures included a range of assessments, tapping on all WHO ICF levels including Oral Confrontation-Naming Task of Snodgrass and Vanderwart Pictures (Rossion & Pourtois, 2004), ASHA Functional Assessment of Communication Skills for adults (Frattali, Holland, Thompson,

Wohl, & Ferketic, 1995), Stroke and Aphasia Quality of Life scale (Kartsona & Hilari, 2007; Efstratiadou et al., 2012).

The Present PhD and change from original design

This PhD project aimed to investigate the efficacy of ESFA - the word level naming therapy used in Thales. The original plan of the Thales project was to investigate the word naming therapy in three different approaches: direct – individual therapy; indirect – group therapy; and combination – individual and group therapy. However, based on methodological and pragmatic considerations two changes were made to the original protocol by the Thales speech language therapy group, with the contribution of the PhD student. Firstly, the delivering approaches were modified from three to two, as therapy delivered only in a group format was not acceptable to the Greek participants with aphasia. Secondly, a control / delayed therapy group was introduced into the study. Both changes are further discussed in the Methods chapter.

The next chapter defines aphasia, overviews the context of aphasia therapy, describes the naming deficits in aphasia and relevant therapy, and presents the Semantic Feature Analysis therapy in detail.

Chapter 1: Introduction

1.1 Definition of aphasia, clinical classification of type and severity

During the history of aphasiology, many definitions of aphasia have been proposed, describing aphasia as a multidimensional concept. Varied aphasia definitions may reflect the wide range of symptoms included under the aphasia label. Different theoretical perspectives have led to different definitions. From a neurological perspective, aphasia is an acquired language impairment. As Damasio (1992) and Goodglass and Kaplan (1983) reported, it is an acquired language impairment because of a focal brain lesion in the absence of other cognitive, motor, or sensory impairments. This language impairment can be present in all language components, phonology/ morphology/ syntax/ semantics/ pragmatics, in the expression and comprehension and across all modalities, such as speaking / reading / writing / signing. The language symptoms of a person with aphasia (PWA) may help identify lesion location, which possibly suggests a specific brain pathology (Damasio, 1992; Goodglass & Kaplan, 1983). From a neurolinguistics perspective, aphasia is a breakdown in specific language domains resulting from a focal lesion (Lesser, 1987). From a cognitive perspective, aphasia is considered the selective breakdown of language processing itself, of underlying cognitive skills, or of the necessary cognitive resources, resulting from a focal lesion (Ellis & Young, 1988; McNeil, 1982). Lastly, from a functional perspective, aphasia is a communication impairment masking inherent competence (Kagan, 1998). For the purposes of this study, the focus is on the International Classification of Functioning, Disability, and Health (ICF; World Health Organization [WHO], 2001) model. Thus, our attention is given not only to the impaired language functions, but also to the impact that these impairments have on the person's communicative and social functioning and quality of life (Martin, Thompson, & Worrall, 2008). In the current study, aphasia is defined as "an acquired selective impairment of language modalities and functions resulting from a focal brain lesion in the language-dominant hemisphere that affects the person's communicative and

social functioning, quality of life, and the quality of life of his or her relatives and caregivers”. (Papathanasiou, Coppens & Davidson, 2016, p.4).

Many classification systems have been proposed for describing individual components of aphasia. Classification of aphasia presentations allows a general description of the presenting symptoms, without the need of detailed explanation of the nature of the symptoms. There is considerable variability in all classification systems and this should be taken into account when examining the information provided. In the present study, two closely related classification systems are used. The first is the Boston Diagnostic Aphasia Examination (BDAE) (Goodglass & Kaplan, 1983) classification system and the second is the ‘fluent / non – fluent’ dichotomy (Gordon, 1998). The BDAE will be presented in detail in the methods chapter. The ‘fluent / non – fluent’ classification represents the volume of verbal output production of a person with aphasia (PWA). The BDAE classification system is the only translated and cultural adjusted standardised measurement of aphasia in Greece. Combining the two classification systems, Global Aphasia, Broca's Aphasia, Transcortical Motor Aphasia and Mixed Aphasia are classified as non-fluent aphasias, while Transcortical Sensory Aphasia, Wernicke's Aphasia, Conduction Aphasia and Anomic Aphasia are considered fluent aphasias (Kertesz, 1982). Global aphasia affects 25 - 32% of PWA and is the most common type within the acute period. Each of the other aphasia types described in the BDAE system occurs less frequently and, as recovery takes place, aphasia types might evolve from one to another (Godefroy, Dubois, Debachy, Leclerc & Kreisler, 2002; Laska, Hellblom, Murray, Kahan & Von Arbin, 2001; Pedersen, Vinter & Olsen, 2003). In many cases, it is difficult to determine the type of aphasia and some aphasias cannot be assigned to the classic categories. Thus, they are reported as unclassified or mixed aphasias. Godefroy et al. (2002) reported approximately 25% of patients as having non-classified aphasias.

Aphasia also can be classified depending on its severity as mild, moderate or severe, based on clinical assessment of the impairment of language modalities (Sarno, 1969). In general terms, mild aphasia is described as a language deficit whereby the person can use language and communicate with a small amount of support and is

successful in approximately 75% of their interaction attempts. Moderate aphasia is defined as a language deficit in which a person requires a medium level of support to successfully interact for approximately 50% of the time. Severe aphasia is described as a language deficit whereby a person requires a substantial amount of support to successfully communicate for up to 25% of the time (Sarno, 1969).

1.2 Extent of the problem: Stroke and aphasia

Each year, 152,000 stroke episodes occur in the UK (Stroke Association, 2015). This equates to more than one event every three minutes and 27 seconds. There are more than 1.2 million stroke survivors in the UK. In Greece, statistics about stroke incidence could only be found from two studies (Vasiliadis & Zikic, 2014; Vemmos et al., 1999). They reported that the annual incidence of stroke in Greece was high. In a population of 100,000, the first study showed that 261 people had a stroke, while the second one found a higher incidence of 319 individuals. Throughout the observation period, between 1998–2002 and 1993–1995, these studies reported a 26.5% mortality rate during the first 28 days and 36.8% by the end of the follow-up period, in Xanthi and Arcadia province respectively.

On discharge from the hospital, approximately 30–35% of stroke survivors have aphasia, with the prevalence of speech (dysarthria) and language (aphasia) disability 6 months after stroke ranging 30–50 per 100,000 individuals (Dickey et al., 2010; Enderby & Davies, 1989; Engelter et al., 2006). Aphasia may often co-occur with other communication disorders, such as dysarthria (slurred speech) or verbal dyspraxia (motor-speech planning disturbance). Speech, language and communication deficits may affect over 80% of people with stroke admitted to an acute hospital facility (Nakayama, Jorgensen, Pedersen, Raaschoo & Olsen, 1997).

People with aphasia have higher healthcare costs (8.5% or \$1,700 attributable cost) and longer length of stays in the hospital (6.5%) compared to stroke survivors without aphasia (Ellis, Simpson, Bonilha, Mauldin, & Simpson, 2012). Stroke survivors

with aphasia are less likely to survive than those who do not have aphasia (Laska, Hellblom, Murray, Kahan & Von Arbin, 2001). Additionally, the presence of aphasia is a poor prognostic indicator for good rehabilitation outcomes (Astrom, Adolfson & Asplund, 1993). People with aphasia have poor long-term outcomes after stroke, including consequences such as social isolation and poor quality of life for themselves and their family members (Cruice, Worrall, & Hickson, 2006; Enderby & Davies, 1989; Grawburg, Howe, Worrall, & Scarinci, 2013; Hilari & Byng, 2009; Hilari, Needle & Harrison, 2012; Northcott, Moss, Harrison & Hilari, 2016).

Aphasia is also associated with higher levels of post stroke depression (Kauhanen et al., 1999; Kauhanen et al., 2000), which has been shown to have a great impact on the individual, family unit and the community as a whole (Godefroy et al., 2002).

It is also important to mention that the severity of aphasia has a considerable influence on the recovery. Prevalence data indicate that of the 44% of people who initially present with severe aphasia after their first ischaemic stroke, 20% remain severely aphasic at twelve months. On the other hand, it is reported that 39% of all aphasic stroke survivors fully recover at twelve months. Epidemiological studies (Pedersen et al. 1995; Pedersen et al., 2003) suggest that those with mild to moderate aphasia are more likely to achieve a better recovery within the first twelve months when compared to those with severe aphasia.

Aphasia can also be described as chronic (Sarno, 1991), when its presence is persisting for longer than one year after the onset of symptoms (Moss & Nicholas, 2006). As a chronic disability and given the negative consequences related to aphasia, PWA are in need of a number of long-term services. Speech and Language Therapy is essential to improve PWA's communication disability (Basso, 2005). It targets the impaired language and communication skills of people with aphasia to enable them to achieve functional and socially relevant communication (Worrall et al., 2011).

1.3 Cognitive Impairment in Aphasia

As indicated in section 1.1, aphasia is an acquired disorder that affects language abilities, including production or comprehension of speech and the ability to read or write. An acquired disorder indicates that there is a consequence of brain damage that affects the neural structures and circuits that are responsible for supporting the language ability. These neural circuits do not only support language, but also sub serve other extra linguistic cognitive skills (Brownsett et al., 2013; Meyer, Cunitz, Obleser, & Friederici, 2014). Language is a complex cognitive skill, as stated in the review of Salako and Imauzue (2017). A complex cognitive skill cannot occur in isolation. A growing body of literature reports evidence that they co-occur with other cognitive impairments (El Hachoui, Visch - Brink, Lingsma, van de Sandt - Koenderman, Dippel et al., 2014; Turgeon & Macoir, 2008; Salako & Imauzue, 2017). Language and other cognitive functions are interrelated and this needs to be taken into account during aphasia assessment and intervention procedures (Turgeon & Macoir, 2008; Salako & Imauzue, 2017).

Guilford and Hoepfner reported in 1971 that cognitive abilities allow a human to process, store, and utilize incoming information. Most models of cognition identify visuospatial skills, attention, memory, and executive functioning as key components (Mayer, Mitchinson & Murray, 2016). This section briefly covers the extra - linguistic cognitive functions that are essential for language processing such as attention, memory and executive functions.

Attention in PWA has been extensively examined in recent years, as attention is considered the foundation of the other cognitive domains (Mayer, Mitchinson & Murray, 2016). Various types of attention have been described: a) sustained attention, which allows us to maintain our attention and have a stable performance for a long period of time, b) switching attention, i.e. moving our attention focus in a precise and valid way from one stimulus or task to another, c) selective or focused attention, that allows us to concentrate on and prioritize a specific point, and d) divided attention, which is an advanced attention function that allows us to attend and perform more than one task

(Murray & Kean, 2004). Thus, attention is an important complex skill that is required for both language comprehension and production (Murray, 2012). Literature findings provide evidence that attention deficits may either be a part of or co-exist with aphasia. A variety of attention deficits have been reported in aphasia, where most studies have focused on a specific attention type (i.e., sustained, selective, divided attention) or modality (auditory, visual). Based on the brain damage of individuals with aphasia they perform less accurately and more slowly on some or all attention skills (Murray, 2012; Villard & Kiran, 2015).

A large number of studies have tested the relationship between aphasia and memory. Findings suggested that there is a possible association between working memory capacity and comprehension in people with aphasia, as memory problems are the most frequently reported cognitive change after a left hemisphere stroke (Visser-Keizer, Jong, Deelman, Berg & Gerritsen, 2002). Impairment can occur at any of the three memory processing stages – encoding (involving acquisition and consolidation of information), storage (creation and maintenance of permanent records of information) and retrieval (employing the previous stages to create a representation of the memory) (Parkin, 2001; Robertson, 1999). Multiple memory subtypes have been tested, such as nonverbal and verbal declarative memory (Beeson, Bayles, Rubens & Kaszniak, 1993; Vukovic, Vuksanovic & Vukovic, 2008); nonverbal and verbal working memory (Friedmann & Gvion, 2003; Jee et al., 2009; Mayer & Murray, 2012; Potagas, Kasselimis & Evdokimidis, 2011); nonverbal learning and encoding (Valilla-Rohter & Kiran, 2013); and nonverbal and verbal short term memory (Baldo, Katseff & Dronkers, 2012; Fucetola, Connor, Strube & Corbetta, 2009; Laures-Gore, Marshall & Verner, 2011; Ronnberg, Larson, Fogelsjoo, Nilsson & Lindberg, 1991). There is heterogeneity of viewpoints regarding the nature, direction, and strength of the association.

On the other hand, researchers generally agree that working memory has a central role in language processing in people with aphasia. As Seniow, Litwin and Lesniak (2009) reported, working memory is necessary for a wide range of complex activities, e.g., in a language comprehension activity we have to recall previous words in a sentence.

So, deficits in the area of working memory have an impact at the language outcome. Aphasia therapy is a learning process where adequate memory processes are required to remember the newly learned information (Helm-Estabrooks, 2002).

Executive functions are responsible for the step-by-step process of planning and coordinating an idea or action. Executive function difficulties include planning and problem-solving difficulties, problems detecting and following rules, error detection and / or awareness. These complications may be more persistent compared to other cognitive problems (Fucetola et al., 2009; El Hachoui et al., 2014; Murray, 2012; Vukovic et al., 2008). A growing body of research suggests that communicative success of PWA might depend on the integrity of executive function skills (Bonini & Radanovic, 2015; Conner, MacKay, White, 2000; Ramsberger, 2010). Moreover, literature findings (Brownsett et al., 2013; El Hachoui et al., 2014) indicate that executive function deficits can affect negatively people's response to rehabilitation leading to worse functional outcomes.

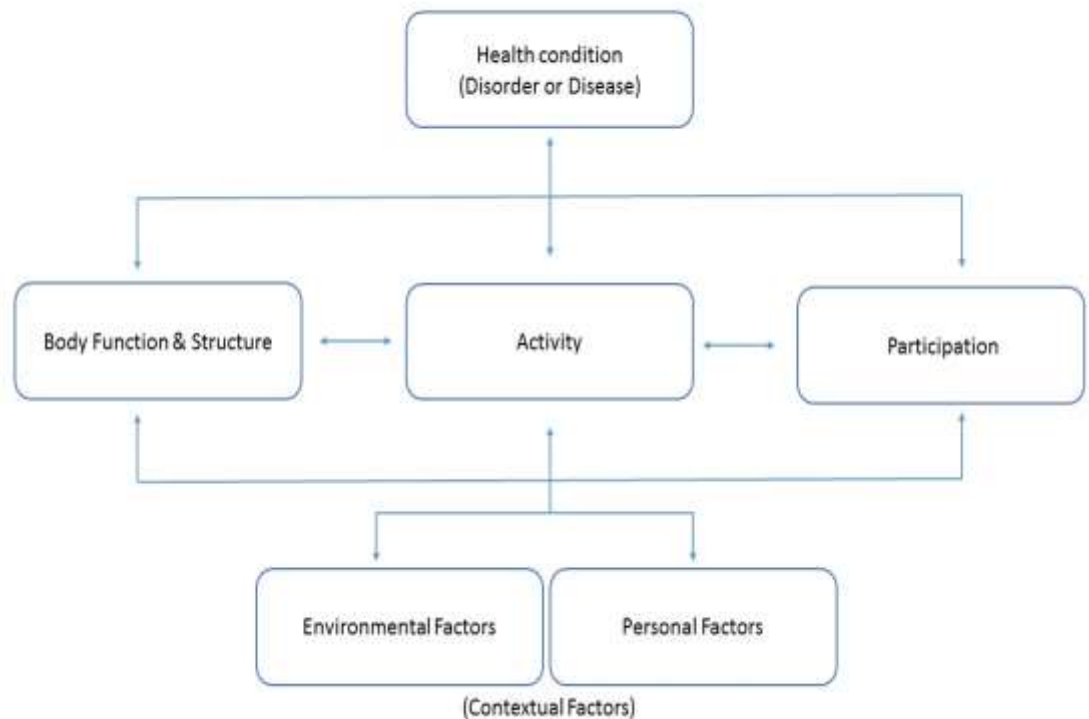
All cognitive functions are required and used during the rehabilitation process in aphasia. Attention is a powerful variable as it is needed in all activities. An inability to attend results in failure to process information. Aphasia therapy is a learning experience and learning relies on memory processes. Executive functions, like problem – solving are required for improving individuals' ability to communicate within everyday settings. In conclusion, since cognitive impairments co-occur with aphasia and influence recovery and response to aphasia therapy, it is recommended that a comprehensive aphasia evaluation should include assessment of attention, memory, and executive abilities (Milman & Holland, 2012; Murray & Clark, 2015). As indicated in the introduction to this thesis, in the Thales Aphasia Project cognitive processes, their inter correlations with aphasia, and their impact on aphasia recovery were comprehensively evaluated in the Neuropsychological Stream. Therefore, they will not be covered further in this thesis.

1.4 Conceptual model of disability in aphasia

There are various models of disability, but the most widely used and accepted internationally is the conceptual framework of the World Health Organizations (WHO), the International Classification of Functioning, Disability and Health (ICF, WHO, 2001). The ICF or otherwise the biopsychosocial approach as it is called, provides a useful framework for treating aphasia in a holistic way, as it combines the medical and the social models of disability.

The primary concepts of ICF, are two: (1) the disability or functioning of the person presenting with the health condition and (2) the contextual factors that can influence a person's disability in a positive or negative way. These two parts are further broken down. More specifically, Functioning and Disability focuses on three main components, as shown in Figure 1: body function/structure, activity, and participation. Body function/structure describes the current level of function due to aphasia. Activity refers to the person's ability to complete tasks or actions. Participation incorporates an individual's ability to fulfil life roles. The Contextual factors include environmental and personal aspects. The environmental factors are seen as these factors that are beyond a person's control, such as relationships with others, policies and regulations, the availability of assistive technology. ICF considers only those environmental factors that influence the effect that impairment might have on activity and participation levels. The personal factors refer to personal information of the person with the condition such as gender, age, educational level. The personal factors are not specifically coded in the ICF because of the wide variability among cultures. They are included into the framework, however, because although they are independent of the health condition they may have an influence on how a person functions.

Figure 1.1: ICF Model of disability



WHO, 2001

In terms of the ICF, an individual with aphasia may have a language impairment (e.g. lexical access difficulties), communication activity limitations (e.g. conversation difficulties with others) and participation restrictions (e.g. relationship restrictions). The contextual factors may act as a barrier or a facilitator for the person with aphasia. Observing aphasia through the ICF framework helps clinicians and researchers to focus on the core features of health and to understand aphasia within the context of real – life.

ICF framework is not a linear model, as shown in Figure 1.1. The arrows indicate that the components are multidirectional and factors influence each other. This means that, by working on one level, therapy gains can be brought in other levels too. For example, an aphasia word-level therapy, which directly targets the impairment level, may have an effect on activity or/and participation aspects. In summary, ICF provides a conceptual framework for human functioning and can be used as a map for a treatment plan for people with aphasia.

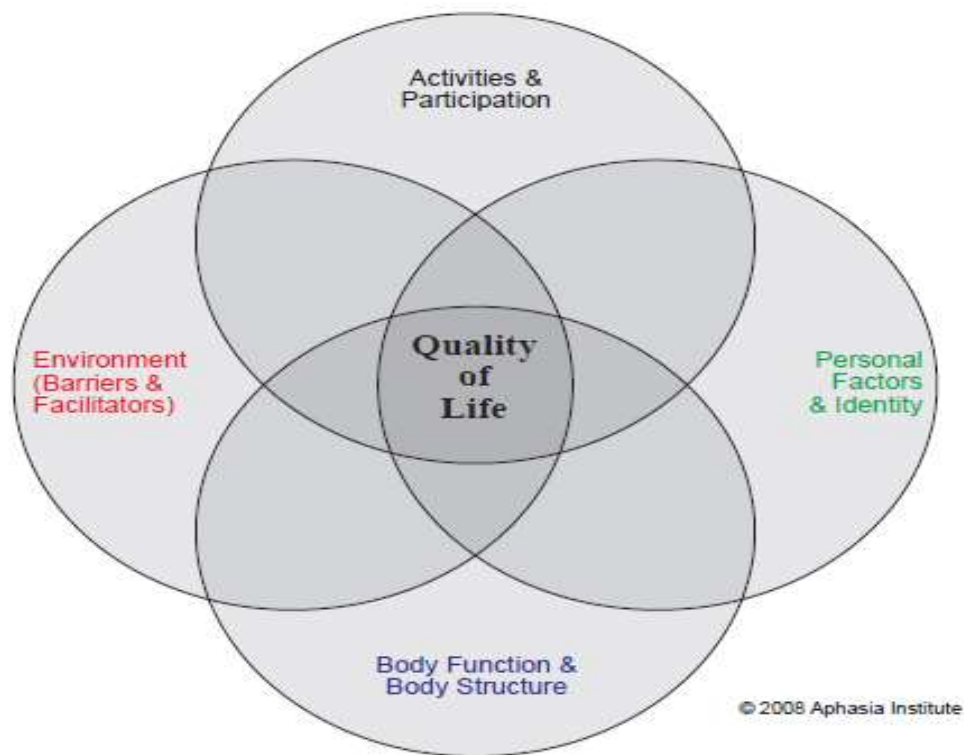
One important factor that is not included in the ICF is quality of life. Bowling (1995) described quality of life (QoL) as a broad and highly subjective concept that can incorporate all aspects of an individual's life. The World Health Organization (WHO) defines QoL as: *an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in complex ways by the person's physical health, psychological state, level of independence, social relationships, and their relationships to salient features of their environment.* (WHOQOL Group, 1995, p. 1405)

Kagan et al. (2008) created the A-FROM. The A-FROM is a conceptual framework adapted from the WHO ICF. It provides a user-friendly representation for thinking about outcomes in aphasia (see figure 1.2). It is in line with values of the Life Participation Approach to Aphasia (Chapey et al., 2001). The A-FROM was not designed for interventions based on a social model; rather, it addresses the lack of an integrated approach for outcome evaluation. The A-FROM captures the domains across various aphasia interventions and outcomes and presents them in an accessible and explicit format for an easy practical application. It consists of five domains: a) the Participation Domain, which includes the life situations specific to an individual, b) the Aphasia Severity Domain, which correlates with the Impairment / Body Function domain of the ICF; it includes outcomes in the realm of language and cognitive processing, c) the Language and Communication Environment Domain, which correlates with the Environmental Context of ICF; it includes aspects of external context that might facilitate or impede language, communication or participation of people with aphasia, d) the Personal Factors/Identity Domain, which includes ICF factors such as age, gender, culture, but expands the ICF Personal Factors domain to include internal factors that vary as a consequence of aphasia, e.g. identity and e) the Life with Aphasia Domain, which captures elements of quality of life. The A-FROM makes an explicit statement about the quality of life in aphasia, as quality of life outcomes involve the dynamic interaction of multiple life domains and is intersected by the four domains (Kagan et al., 2008). The deliberate use of overlapping circles, rather than separate boxes with arrows, suggests the

real-life overlap and interaction among the four domains, creating a comprehensive picture of quality of life in aphasia.

In the context of the ICF framework and the A-FROM model, therapy can target any component of this dynamic process. The aim of therapy should be to reduce the overall burden of aphasia, resulting from the impairment itself, activity limitations, or/and participation restrictions. Therapies that focus on the “body functions and structure” or the “severity of aphasia” domain, are typically called impairment – based therapies. When the focus shifts towards the activity and participation domains, then therapy is known as socially oriented/ communication – based/ functional – based.

Figure 1.2:A - FROM domains



Kagan et al., 2008

In the literature, some studies have reported benefits for functional domains, even in cases when an impairment-based therapy was administered, without targeting functional outcomes directly. Such an example was the study of Best, Greenwood, Grassly & Hickin (2008), where eight participants who completed a course of word finding therapy reported higher ratings in communication during participation activities after the end of therapy. Moreover, four participants in this study showed a positive change with respect to ‘emotional consequences’, while one remained stable, and two held less positive views.

In the present research, all the domains of the ICF framework are tested, as well as quality of life. One of the aims of the current study is to examine if an impairment - based therapy can lead to secondary benefits, as was reported in Best et al. (2008) study.

1.5 Word Production Impairments

Word – finding difficulties are common across aphasia types. It is the most common symptom of aphasia and it is called anomia. Anomia was described by Goodglass (1993) as the impaired access to one’s vocabulary. Anomia is characterised by difficulty in recalling words or names and it usually becomes noticeable through production of paraphasias, neologisms, jargon, and circumlocutions. Semantic paraphasias consist of word choice errors (e.g. fork for knife); while phonemic paraphasias consist of sound errors (e.g. ear for tear). Circumlocutions occur when an individual uses description, definitions, or sounds to convey target words (e.g. for wardrobe ‘where you put your clothes in’). Finally, neologisms are non-word productions (e.g. kinefit). Jargon is a more severe word retrieval deficit in which the speech produced is full of neologisms (Murray & Clark, 2006). The nature of the underlying impairment in word – finding or naming difficulties is not uniform across aphasia types. They can result from impairments at different stages of the naming process: decoding, storage, selection, retrieval or encoding (Benson & Ardilla, 1996; Goodglass, 1993; Whitworth,

Webster & Howard, 2005). Aphasic naming errors can differ and some differences may be related to the type of aphasia an individual has. For instance, naming may be hindered because of impaired access to semantic networks, as happens in Broca's aphasia, or because of a disruption to the semantic networks themselves, as in Wernicke's aphasia. Most, if not all, PWA experience word-finding difficulties to different extents and in various contexts of speech production, ranging from naming tasks to conversation tasks.

1.5.1 Theoretical Basis of Naming Deficits

The cause of naming deficits in PWA can be understood better by considering theoretical models of naming (Dell et al., 1997; Levelt et al., 1999). Caramazza and Berndt (1978) summarise the naming process through three main stages: the encoding stage, in which a stimulus and its identifying features are perceived, the central stage, consisting of an initial mapping of information onto the stimulus' semantic representation/conceptual category, followed by a secondary mapping of the concept to a specific lexical item/the object's name and, finally the production stage that guides the articulation of the correct phonological sequence. Anomia can be the result of impairment(s) in one of the following three networks: access to word-specific semantic features (semantic network), retrieval of the word form (lexical network), and encoding of the corresponding phonemes of that word (phonological network). It is difficult to assess and find the level of impairment because the above three networks represent stages of the naming process, with the possibility of some or all of them to be impaired at the same time (Chialant, Costa & Caramazza, 2002; Davis, 2007; Raymer & Gonzalez-Rothi, 2000).

Word production can be described with different models, like the discrete stage model of Levelt and colleagues (1999) (see Figure 1.3), the interaction activation model of Dell and colleagues (1997) (see Figure 1.4), the cognitive neuropsychological model of lexical processing (Ellis & Young, 1988; Whitworth, Webster & Howard, 2014) (Figure 1.5). In the discrete stage model, the steps involved in word production occur independently. This model consists of five levels: the conceptual –semantic

representations, the lexical – semantic representations, the lexical – form representation, the phonological encoding, and the articulation stages. Word production begins with the conceptual – semantic representation level, where a concept, which is in its non - linguistic form, is stimulated, while word retrieval starts with conceptually driven activation of the semantic features of the word. At the second stage, the word form of the associated semantic feature is selected from the mental dictionary. At this stage, activation in the lexicon takes place not only for the target word, but also for related words such as synonyms, associated words, category coordinated, and super- or sub-ordinate words. One of the activated words is selected for oral production. The phonological encoding stage follows, where the sounds of the word are retrieved and ordered. The last stage of the model includes the process of word articulation. According to Levelt's model, naming is a serial process, in which there is limited interactivity between processing levels during word retrieval. There are only feed forward patterns of activation from the lexical to phonological processing levels. Naming is a discrete process in the sense that the activation is confined to a particular processing level until the selection of targeted concepts has been completed. Therefore, the early stages of naming involve activation of semantic processes, while the latter stages of naming involve activation of phonological processes.

In the interaction activation model, the word retrieval stage is similar to that described in Levelt and colleagues' (1999) model. This model has six levels: the conceptual –semantic representations, the semantic feature network, the lexical network, the phonological network, the phonological encoding and the articulation. According to Dell and colleagues (1997), naming is initially a serial and interactive process. Interaction occurs because both feed forward and feedback patterns of activation are possible. Moreover, activation can be spread from each processing level, before any single candidate has been explicitly selected; it allows multiple candidates at each level to transmit activation to the subsequent level. Thus, while the early stage of naming involves activation of semantic processes, the latter stages of naming are characterised by activation and interaction of both semantic and phonological processes.

Both models demonstrate that lexical access involves activation of semantic and phonological processes. Lexical access is concluded with two sequential components: lexical selection and phonological encoding. However, Dell (1992) proposed that lexical access can have two levels, but not necessarily two stages, as it involves two closely interacting levels in one stage: activation of the semantic representation and activation of the phonological form of the target word.

The cognitive neuropsychological model of lexical processing (Ellis & Young, 1988; Whitworth, Webster & Howard, 2014) gained wide acceptance among the aphasia research community (Wilshire, 2008). It is one of the most successful models for explaining language deficits in aphasia, as it incorporates visual and auditory input and output processes into its framework (Wilshire, 2008) and enables clinicians to identify specific levels and modalities at which language processing breaks down. Thus, the model is applicable for receptive and expressive language deficits. This model explains the process of how visual, auditory or pictorial information are entering into and retrieved from the semantic system. The emphasis in this model is given in a central semantic system which is interconnected, for both input and output processes, with separate memory stores of phonological and graphemic word forms. For this PhD only the process of naming a picture will be explained. In order to name a picture of e.g., a 'chair' the item firstly must be presented to the semantic system via the visual object recognition system. Once the information arrives at the semantic system, which identifies the representation or meaning of /chair/, the phonological output lexicon is activated in order to retrieve the phonemes form that represents /chair/. As the phonemes are retrieved, the phonological output buffer acts as brief temporary storage that holds phonemes as words are formed. After the phonemes are properly sequenced, the word is finally pronounced. The use of this model in the analysis of naming difficulties allows clinicians to identify the specific levels and modalities at which language processing breaks down.

Figure 1.3: Discrete – Stage Model of Word Production (Levelt, Roelofs & Meyer, 1999)

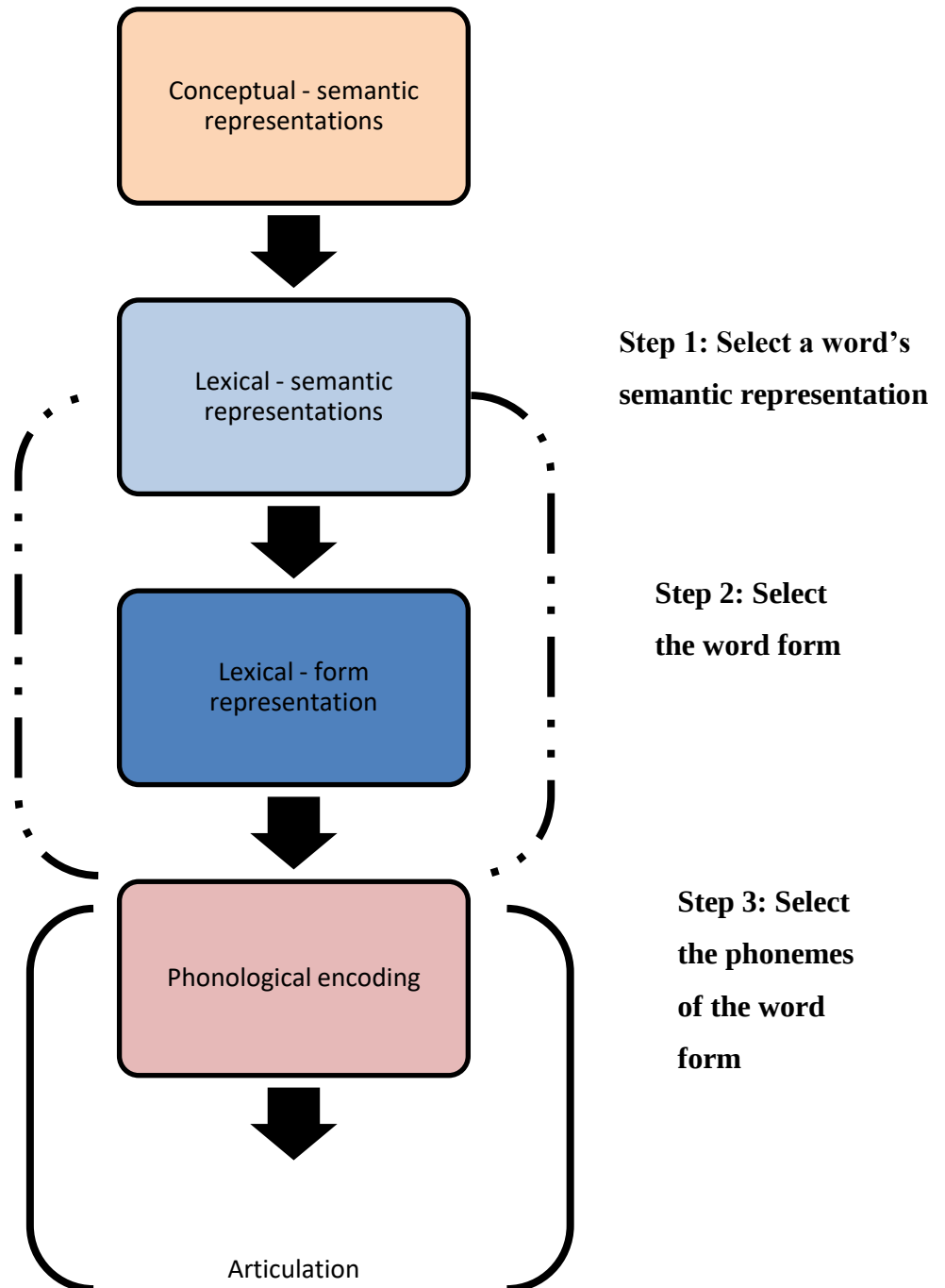


Figure 1.4: Interactive Activation Model of Word Production (Dell et al., 1997)

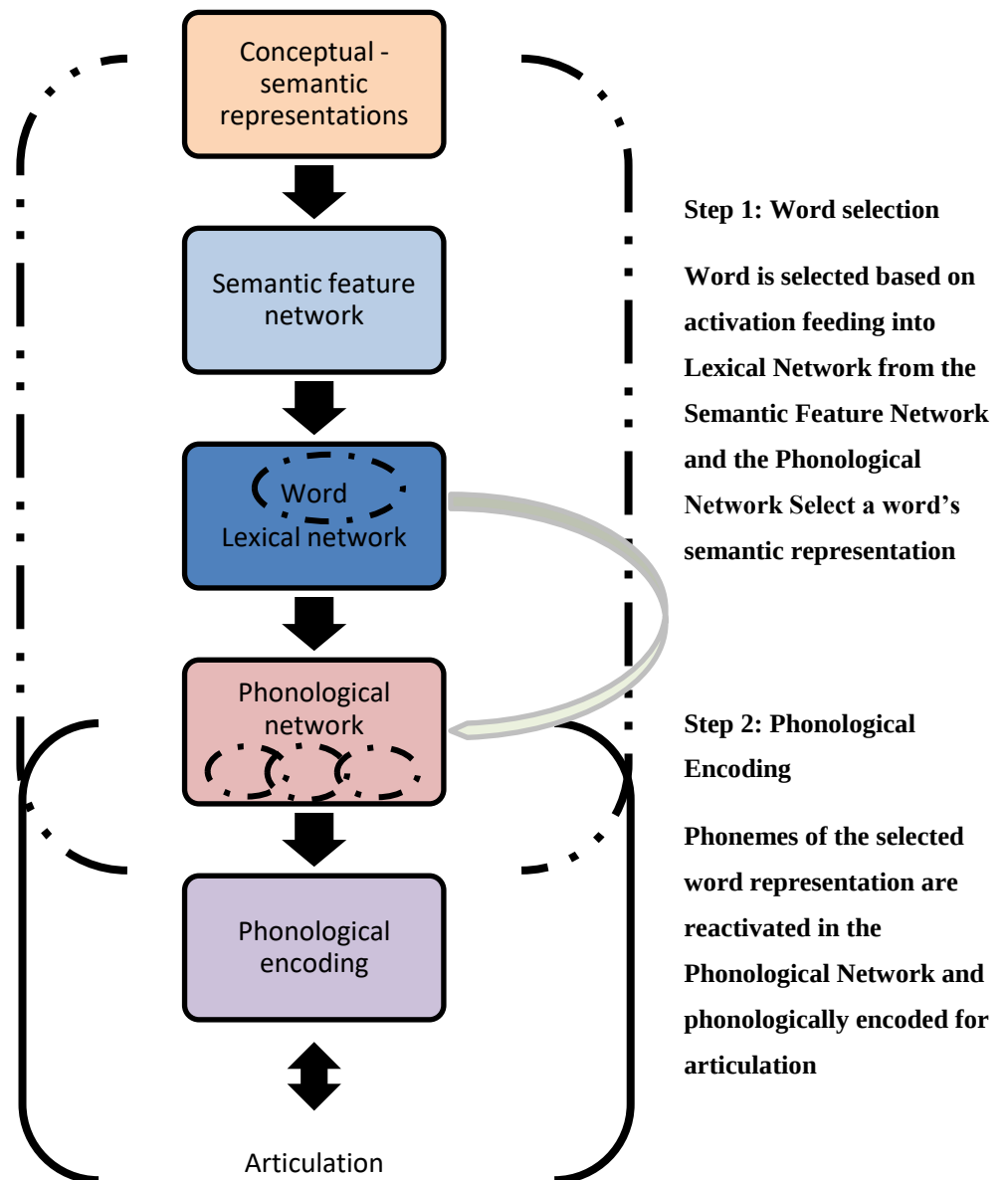
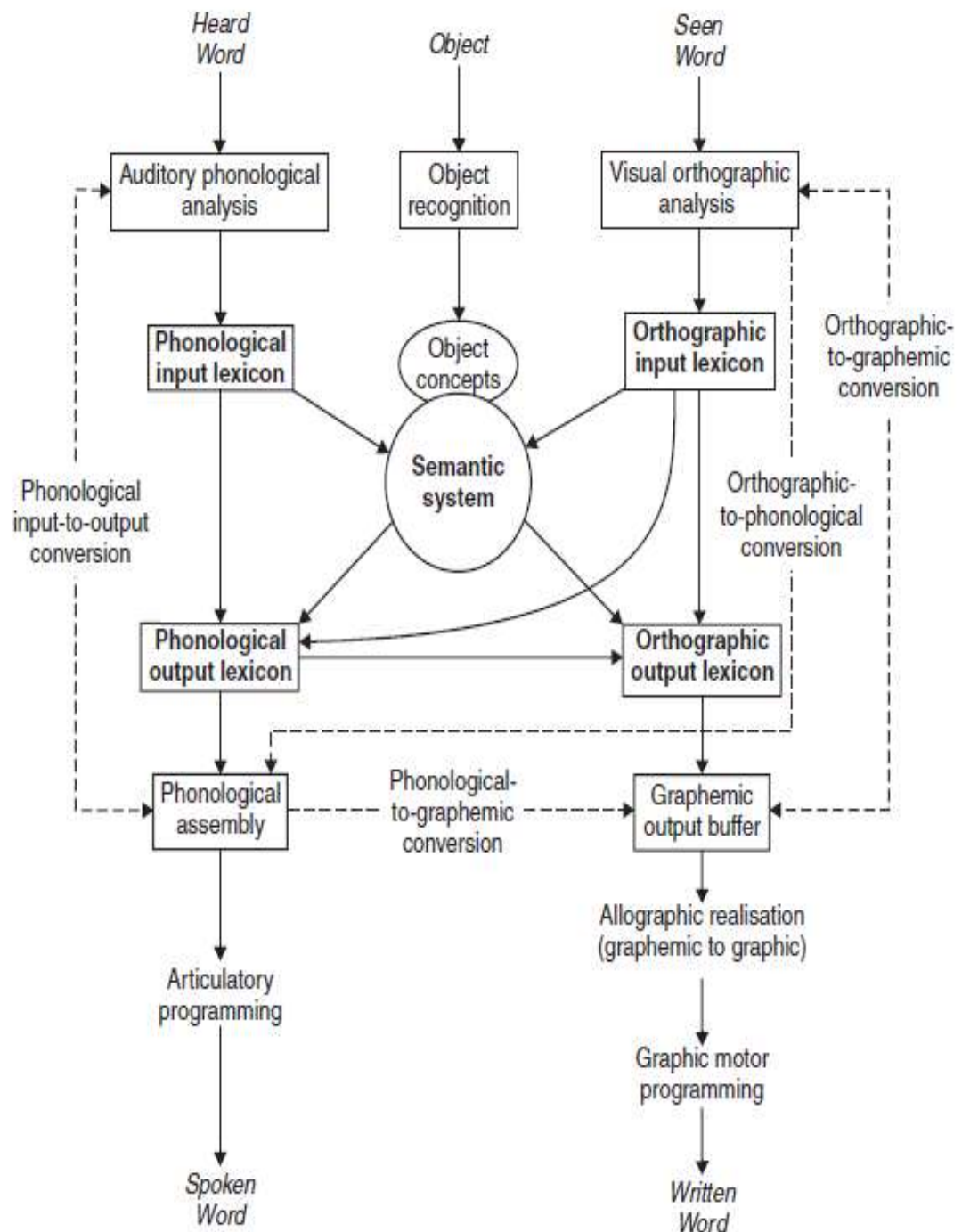


Figure 1.5: Cognitive Neurological Model of Lexical Processing System (Ellis & Young, 1988; Whitworth, Webster & Howard, 2014)



Naming deficits in aphasia can arise either from incorrect/incomplete activation of semantic or phonological information (Dell et. al., 2004; Schwartz et. al, 2004; Schwartz et. al, 2006). The inability to retrieve a word for production can arise from damage to semantic processes, access from the semantic level to the phonological level, phonological encoding, or any combination of the above (Fink, Brecher, Schwartz, & Robey, 2002). In the following paragraphs, a description of the various types of anomia resulting from specific deficits in different possible levels is given, based on the cognitive neurological model.

Deficit in the semantic network – lexical semantic anomia

A deficit in the semantic network would cause incorrect naming. Individuals with semantic anomia mainly produce semantic paraphasias, such as table for chair and pear for apple. They might show an imageability effect, with better production for high-imageability (concrete) words than for low-imageability (abstract) words, and a typicality effect with more typical items of the category, e.g. apple, more easily produced compared to less typical ones, like plum (Cohen-Shalev & Friedmann, 2011). Due to the fact that the semantic lexicon is most likely shared in production and comprehension processes, individuals with impairment in the semantic lexicon fail not only in word retrieval, but also in the comprehension of written and spoken words. They perform well in picture tasks, such as picture odd-one-out and picture association, but they fail in tasks that involve words. Thus, they encounter difficulties in written and spoken word versions of the odd-one-out and word association tasks. Because semantic anomia is rooted in the semantic network, individuals with this type of anomia read and repeat non-words correctly, and do not produce phonological paraphasias during naming.

Deficit in the phonological network – lexical phonological anomia

A deficit in the phonological output lexicon causes incorrect naming. Individuals who are impaired in this level understand concepts well, and can access corresponding representation to the semantic lexicon, but fail to activate the correct entry into the phonological output lexicon. Thus, they produce phonological paraphasias. Typically, these individuals not only produce phonological paraphasias, but also semantic

paraphasias, possibly because they do not have access to the phonological representation of the target word and thus representation of a semantically-related word is activated (Caramazza & Hillis, 1990; Howard & Gatehouse, 2006). As phonological output lexicon is organised by frequency, these people show a frequency effect (Jescheniak & Levelt, 1994), whereby they make more errors in the least frequent target words. Because this deficit lies in a stage that follows the conceptual and lexical semantic ones without affecting the latter, individuals with a deficit in the phonological lexicon perform well in conceptual comprehension tasks using pictures. Given that their deficit is in the phonological output lexicon, which is separate from the phonological input lexicon, they understand heard (and written) words well. They read or repeat non-words, as production does not have to involve the lexicons.

Deficit in the connection between the semantic and the phonological output networks

Impaired naming can result not only from a deficit in the components (semantic or phonological networks) themselves, but also from deficits in the connections between them. A deficit in the connection between the semantic lexicon and the phonological output lexicon results in lexical-phonological anomia, characterised by phonological and semantic paraphasias; but good comprehension of pictures and words and good reading and repetition of non-words. It differs from lexical-semantic anomia in that individuals with the disconnection are expected to understand heard and read words well, but fail in producing them. Lexical-semantic anomia differs from lexical-phonological anomia in that reading can still be done via the phonological output lexicon, and if this is intact reading should not include regularisations of irregular words.

Deficit in the phonological output buffer – phonological buffer anomia

Individuals with phonological output buffer impairment have also word production problems. Their error patterns include phonological errors, but not semantic ones (they may, when failing to produce a word, produce another word instead that is similar in meaning, being aware that it is not the exact word they meant to use). Due to the fact, that their deficit is not related to the conceptual and semantic stages, they have

no problems in comprehension tasks of pictures, written words, or spoken words. They experience a marked difficulty in non – words though, because the phonological output buffer is responsible for holding and composing phonemes of non – words, in reading and repetition tasks. Their difficulty with non - words and new words is often more severe than their difficulty with real words, as non – words do not rely on activations of the lexicon to support their production.

Because the phonological output buffer is a short-term phonological component, it is affected by the length of the phonemic string it holds – strings that are longer than its capacity are affected (Franklin, Buerk & Howard 2002; Nickels 1997), and their phonemes are omitted or substituted. This word length effect indicates the involvement of the buffer, with naming in phonological output buffer anomia being considerably influenced by the length of the target word (unlike deficits in earlier stages). Additional effects that are unique to anomia in the phonological output buffer in the phonetic encoding stage, are the syllable and phoneme frequency effects: individuals with phonological output buffer anomia produce fewer errors in frequent syllables rather than in infrequent syllables, and in frequent phonemes rather than in less frequent ones (Goldrick & Rapp, 2007; Laganaro, 2005). Syllable frequency and phoneme frequency are inter-correlated; Laganaro (2005) found that analysis of syllable frequency is more reliable. The syllable frequency effect is assumed to be caused by failure of access to the mental store of syllables, which holds pre-assembled syllables (Laganaro, 2008).

To summarise, the presented models of word production can help identify the source of naming deficits in a person with aphasia. Furthermore, they can inform development of treatments for individuals with naming impairments (Best & Nickels, 2000). Accordingly, approaches that have focused on improvement of either semantic or phonological processing levels have reported positive outcomes (Nickels, 2002). The next section will present different therapies for naming deficits in aphasia.

1.5.2 Therapies for Naming Deficits

Naming deficit therapies have been a major focus of language rehabilitation research post-stroke (Goodglass & Wingfield, 1997). There are numerous reports of treatment studies of different approaches for word – finding difficulties, with different underlying deficits. Nickels (2002) provided an extensive review of the intervention literature for word retrieval and demonstrated that language treatments focused on the impairment level had a large effect on: noun retrieval (Hillis & Caramazza, 1994; Howard et al., 1985), and verb retrieval (Murray & Karcher, 2000; Raymer & Ellsworth, 2002) with maintenance of some behaviours over time (Pring et al., 1990). Treatments were also shown to generalise to conversation (Hickin et al., 2002). As Martin (2013) stated, examination and development of effective treatments for word finding deficits is an important issue in rehabilitation of aphasia. Many types of therapy for naming disorders exist, including behavioural approaches, therapy to reactivate lexical semantic or phonologic representations, use of alternative cognitive systems, and treatment focused on compensatory strategies (Kiran et al., 2008).

Word – finding treatments aim to strengthen the connections between the semantic and lexical networks or the connections between the phonological and lexical networks, trying to facilitate or remediate processing at and between the damaged component(s). Tasks can be grouped into semantic or phonological, or a combination of both. According to the level of breakdown in word production, different types of treatment may be more effective (Hillis & Caramazza, 1994; Nettleton & Lesser, 1991; Whitworth, Webster & Howard, 2005). For example, if the locus of the naming deficit is in retrieving the meaning of words (semantic) rather than in retrieving the sounds of words (phonological), then the ideal treatment should be focused on the specific deficit (Nickels, 2002).

As indicated above, difficulties in naming due to semantic deficits can be the result of impairment in access to semantic representation or impairment in the area of the lexical-semantic representation (Laine & Martin, 2006). A semantic treatment aims to

improve naming by restoring or strengthening semantic representations, or by priming weak semantic representations (Maher & Raymer, 2004).

Semantic tasks that are described in the literature for improving the naming ability of people with aphasia are the following: a) spoken and written word to picture matching (Byng, 1988; Marshall et al., 1990), b) generating and discussing semantic properties of the object to be named - semantic feature analysis (Boyle & Coelho, 1995; Coelho, McHugh, & Boyle, 2000; Boyle, 2004; Lowell, Beeson, & Holland, 1995) c) semantic feature verification (Kiran & Thompson, 2003), d) generating or matching synonyms (Hough, 1993), e) contextual priming (Martin, Fink, & Laine, 2004; Renvall, Laine, & Martin, 2007) f) making judgments about functions, semantic features, or relatedness of objects (Drew & Thompson, 1999; Nickels & Best, 1996a, 1996b).

A phonological therapy aims to strengthen representations at the level of the word form (Maher & Raymer, 2004), or strengthen connections between the semantic system and the word form (Laine & Martin, 2006). Naming impairment due to deficits in post-semantic/phonological processing may be the result of impaired access to the phonological output lexicon, or to the lexical representations themselves (Laine & Martin, 2006). ‘Phonological’ tasks include those that provide information about the phonology of the target (repetition, phonemic cues). Therapy tasks that have been shown to improve naming in people with aphasia include the use of cueing hierarchies and repetition (Raymer, Thompson, Jacobs, & Le Grand, 1993), reading aloud (Eales & Pring, 1998; Howard, 1994; Nickels & Best, 1996a), syllable judgments, initial phoneme discrimination, and rhyme judgment (Franklin, Buerk, & Howard, 2002; Robson, Marshall, Pring, & Chiat, 1998). Repetition is the most common phonological task and is found in the majority of treatments (Nickels & Best, 1996a, 1996b; Nickels, 2002).

Traditionally, ‘semantic’ and ‘phonological’ tasks were thought to have different effects on word retrieval (Mitchum & Berndt, 1995; Nickels & Best, 1996a, 1996b). Results of the early research suggested that ‘phonological’ tasks only improved naming for a very short time (6 items later, with no effects at 10-15 minutes; Howard et al, 1985), whereas ‘semantic tasks’ improved naming for up to 24 hours (Howard et al, 1985).

However, more recent studies have suggested that phonological cues can produce durable effects too (Best et al, 2002). Howard (2000) suggests that the difference between semantic and phonological tasks may be overstated. As Howard (1994) and Nickels (2002) suggested, most treatments comprise tasks that involve semantic, phonological, and sometimes orthographic tasks, although researchers and clinicians often characterise their treatments as taking a semantic or the phonological approach. In the majority of the studies where semantic tasks have been used, the form of the word is provided (as a spoken or written word), and in phonological tasks, a picture is usually present (suggesting semantic processing). For example, in a semantic therapy, like semantic feature analysis (SFA) (Boyle & Coelho, 1995; Coelho et al., 2000; Conley & Coelho, 2003) a word is also provided for repetition. If the subject is unable to retrieve the correct name after describing the various semantic properties of the stimulus object, s/he will be given the target for repetition, which may also activate the meaning of the word. Hence, Howard (2000) argued that the difference between these tasks is indeed more apparent than real and that both tasks are affecting language processing in the same way.

1.6 Treatment types in aphasia

Howard and Hatfield (1987) reviewed historically the types of treatment for aphasia and identified three approaches: surgical, pharmacological and behavioural. Over the last 100 years, the vast majority of treatments in aphasia rehabilitation have been behavioural. There is no evidence that pharmacological therapy in itself, is effective in restoring language deficits (Brady, Kelly, Godwin, Enderby, Campbell, 2016). Behavioural aphasia therapy is the supportive process designed to help people with aphasia modify their current communicative behaviours, with practice to maximise their communicative proficiency. Two approaches to aphasia rehabilitation have emerged during the last few decades; one that focuses on restoring language, the impairment – based therapy approach, and another focusing on the consequences of that impairment, the communication – based therapy/ functionally-oriented or activities / participation-based aphasia treatment.

The impairment – based therapy approach, otherwise disorder oriented, aims to remediate a particular area of language. A cognitive neuropsychological model of aphasia, which describes the cognitive linguistic processes involved, is typically applied in this approach. The aim is to restore the cognitive linguistic processing of the person with aphasia by providing cognitive – linguistic therapy. This approach begins with a linguistic evaluation aiming to identify the disruption of the cognitive linguistic processes of the person with aphasia and then therapeutic tasks aiming to restore the damaged processes follow (Byng, Pound, & Parr, 2000). Therapy may target semantics, phonology, morphology and syntax levels. Main types of impairment-based therapies include: Constraint Induced Language Therapy (CILT), Melodic Intonation Therapy (MIT), word finding treatment, treatment of underlying forms, syntax treatment, verb network strengthening treatment and some reading and writing treatments (ASHA, 2014). Specific therapies have been developed, including therapy for naming disorders (Nickels & Best, 1996) such as, Mapping Therapy (Schwartz, Saffran, Fink, Myers and Martin, 1994), lexical semantic therapy or BOX therapy (Visch-Brink, Bajema & Van de Sandt-Koenderman, 1997) and semantic feature analysis (Coelho, McHugh & Boyle, 2000). Positive effects on language performance have been documented on individuals with aphasia following these types of naming therapy (Thompson & Shapiro, 2005; Wertz et al., 1981; Whitworth, Webster, & Howard, 2005); however, generalisation of therapy gains to functional communication is not well understood (Cermak, 2011). Impairment – based therapy is typically delivered in individual / one – to – one / direct settings. In this type of therapy, intervention sessions are typically didactic and a Request – Response – Evaluation (RRE) sequence is followed. As Simmons – Mackie and colleagues (2007) state, the therapist requests the individual to perform, e.g. asks him / her to name a picture, the individual responds, and the therapist evaluates his/ her response. Impairment – based therapy is typically structured and controlled by the therapist.

Communication – based therapy, in contrast to the impairment-based therapy, is a participation-based or socially oriented approach. The goal of this treatment is associated with improved communication readiness, well-being and self-confidence. This can be achieved with interaction-focused intervention, such as PACE (Promoting

Aphasia Communication Effectiveness) or therapeutic role-playing, dialogue training, the use of strategies and alternative and augmentative training such as gestural cueing (Salter, Teasell, Bhogal, & Zettler, 2012; Ziegler et al., 2008). Treatments that focus on activity and participation include multimodal treatment, partner approaches, pragmatic treatment, reciprocal scaffolding, and script training (ASHA, 2014). The Life Participation Approach to Aphasia (LPAA Project Group, 2000) is the most socially-oriented approach. LPAA encourages reengagement in life throughout the rehabilitation process, and strives to empower the individual with aphasia and to reduce the consequences of aphasia in the individual's quality of life. Intervention that targets activities and participation may improve the quality of life of many individuals with aphasia. Studies have found a higher correlation between the level of participation in daily activities and quality of life in people with aphasia, than between the performance of daily activities and the severity of language deficits (Eadie et al., 2006). Group treatment can be an example of a socially-oriented or participation-based approach. In group therapy, individuals are engaged in functional language tasks, such as group-oriented conversation. Because conversation is not scripted, the participant can choose the way he or she responds to a conversational prompt, fostering a more natural and equal role in the communicative exchange. There is some evidence for the use of conversation group treatments to improve language performance for individuals with aphasia (Elman & Bernstein-Ellis, 1999a; Wertz et al., 1981).

Both impairment/language focused and communication focused interventions seem to improve communication in people with aphasia (Martin, Thompson & Worrall, 2008). A logical assumption would be that a combination of these two intervention types may be more beneficial than each treatment type on its own. To date, limited evidence exists to support their use in a combined intervention manner.

Below, some examples of impairment – based and communication – based therapies, which have been shown to improve discrete language functions in areas of verbal expression, are presented.

➤ Impairment – Based Treatments

A. Semantics

- Semantic feature analysis (SFA) is thought to improve retrieval of conceptual information by stimulating the semantic networks. During semantic feature analysis treatment, the PWA is guided to produce words semantically related to the target. According to the spreading activation theory of semantic processing, activating the semantic network surrounding the target should activate the target itself above its “threshold” level, thus facilitating retrieval of the word. SFA is described in detail below (see 1.8).
- Verb Network Strengthening Treatment (V-NeST) was developed by Edmonds, Nadeau and Kiran (2009). It is a verb-centered treatment designed to promote generalisation of noun and verb retrieval to single words, sentences and discourse. The treatment, based on principles of semantic theory surrounding the interrelationship between verbs and their thematic roles (McRae, Ferretti, & Amyote, 1997), requires participants to generate explicit thematic roles related to trained verbs.
- BOX (Visch-Brink & Bajema, 2001) is a lexical semantic therapy program that aims to stimulate lexical semantic processing by applying the odd-word-out technique in a context of increasing difficulty. It focuses on improving recognition of the semantic features of content words and strengthening the semantic relations between words, rather than on regaining semantic items. Exercises are presented in a multiple choice or right/wrong format and have several levels of difficulty. Individuals are trained on strategies that are assumed to generalise to word retrieval during everyday communication.

B. Phonological

- Phonological Components Analysis (PCA) was developed by Leonard, Rochon and Laird (2008) and it was modelled after the SFA approach. PCA was created to serve as a comparable phonological approach to SFA. PCA treatment followed the protocol of Coelho et al. (2000). The target picture was presented in the centre of a chart and the participant was asked to name it. Regardless of his/her ability to name the picture, the participant was asked to identify five phonological components related to the target item (i.e., rhymes with, first sound, first sound associate, final sound, number of syllables).
- Phonomotor treatment was developed by Kendall and colleagues (2008) (Kendall, Pompon, Brookshire, Minkina, & Bislick, 2013). It directly targets sound production and perception. The treatment is carried out over two stages. Stage 1 includes tasks that involve exploration of sounds, description of motor aspects of sounds, perception of sounds, and production of orthographic representations of sounds. In Stage 1 sounds are practised in isolation. Stage 2 includes tasks like those used in Stage 1, but sounds are no longer practised in isolation. The focus in Stage 2 is on sound sequences.

C. Semantics and phonology

- Cueing Hierarchy was developed by Linebaugh and Lehner (1977) (Linebaugh, Shisler, & Lehner, 2005). This treatment approach has the longest history in aphasia rehabilitation. Cueing hierarchy can be semantic or phonological. Initial sentence completion cues and phoneme cues are the most effective in facilitating the retrieval of an elusive word (Pease & Goodglass, 1978). The aim of cueing hierarchy therapy is to teach people with aphasia to develop internal cueing strategies. Linebaugh (1983) reported that cueing hierarchies begin with the least powerful cue, with the cues that follow to provide increasingly more information; during the therapy procedure

though, the facilitative power of the cues decreases gradually. This approach values stimulation and strengthening of the semantic and phonological connections with the lexicon.

➤ Communication – based therapies

Training communicative strategies

- Promoting Aphasic's Communicative Effectiveness (PACE) was developed by Davis and Wilcox (1985) (Davis, 2005). It is one of the first therapy methods that were called “pragmatic”. It introduces a number of pragmatic aspects of conversation into clinical practice. The combination of four principles makes the interaction during therapy resemble natural conversation: (1) the exchange of new information, (2) equal participation of individual and therapist, (3) free choice of communicative channels – the clinician can apply modelling to encourage certain strategies, (4) functional feedback – the clinician tells whether the message was understood. The content of messages becomes more complex and abstract as therapy progresses, e.g. from cards of objects to newspaper articles.
- Role playing (Schlanger & Schlanger, 1970) enables the person with aphasia to practise communication situations derived from everyday life in a therapeutic setting. The clinician can select appropriate communicative strategies or channels through which the patient tries to communicate.
- Conversational coaching (Hopper, Holland & Rewega, 2002): the aim of conversational coaching is that the client can employ the practised strategies outside the clinical setting. The PWA has to first communicate a script, a short text containing some sentences or a combination of pictures and words, to the clinician. The person with aphasia is directed to apply the strategies they trained on before. Then, the

individual does the same with another familiar person, while being coached by the clinician. The video recording of the conversation is then analysed and discussed with the people involved. Next steps include practising with unfamiliar persons and new scripts.

- Multi-Modality Aphasia Therapy (M-MAT) (Rose, Attard, Mok, Lanyon, & Foster, 2013): the aim of M-MAT is verbal production. M-Mat is a manualized treatment protocol (Rose & Attard, 2011) with the primary treatment objective to facilitate spoken naming rather than multi-modality communication. Thus, naming is practiced along with the addition of gesture, drawing, reading, and written naming cues. Multi-modal treatments exploit the often-preserved drawing, gesture, reading and writing abilities of individuals with aphasia, either as compensation techniques when spoken communication fails to be restored, or as direct cross-modal facilitation techniques to re-establish language and speech.
- Conversational scripts training (Cherney, Halper, Holland, & Cole, 2008): the aim of conversational scripts training is to help people with aphasia to use short self-chosen monologues and dialogues in natural, conversational contexts. Intensive practice leads to more automatic and accurate production of sentences within the script. A software program has been developed, Aphasia Scripts. It uses an animated agent that serves as a virtual therapist for script training for individuals with aphasia. The virtual therapist is programmed to produce natural speech with correct movements of the speech articulators (Cole et al., 2003). Aphasia Scripts provides repeated opportunities for the client to practice individualized conversations that have been pre-recorded. Practice occurs with various forms of assistance (written word, choral speaking, oral-motor movements of the virtual therapist), depending upon the clients' needs.

1.7 Group Aphasia Treatment

Positive effects of individual therapy have been documented, but generalisation gains in functional communication skills are not well understood, as no gains in other communicative environments, such as home, work, and society have been reported (Lyon, 1992; Kearns, 1989; Thompson, 1989). Group therapy is often viewed as an extension of the individual therapy, where the focus is given on the generalisation of the communication skills to real – life environments (Elman & Bernstein – Ellis, 1999a, 1999b). Group treatment offers a more naturalistic environment, which fosters pragmatic skills and helps people with aphasia build relationships through sharing experiences (Davis, 1986; Wilcox, 1983). Advantages of group aphasia treatment have been reported by Elman (2007a).

According to Elman and Bernstein-Ellis (1999b), group treatment “facilitates generalisation of functional communication to natural environments” (p. 412). Research confirms that aphasia group treatment mirrors everyday communicative events by utilising a variety of discourse management features. These features help by “establishing the feeling of discourse equality, focusing on everyday communicative events and genres, employing multiple communication modes, mediating communication, calibrating corrections, aiding turn allocation, and judiciously employing teachable moments” (p.18, Simmons-Mackie et al., 2007). A group setting creates a supportive environment, reducing stress and providing an opportunity for peer assistance and modelling. The different members provide each participant with multiple communication partners and opportunities for using multimodalities in a natural communication setting (Simmons-Mackie & Damico, 2009; Marshall, 1993).

Group treatment is a broad classification that includes psychosocial groups, speech-language therapy groups, family counselling and support groups, and multipurpose groups. Psychosocial groups focus on providing participants with a social atmosphere that gives support and shows understanding, facilitating acceptance of aphasia (Kearns & Elman, 2001). Speech and language groups can be structured to provide direct, indirect, sociolinguistic, transitional, or maintenance training (Kearns &

Elman, 2001). Family counselling and support groups provide education about a given disorder or disease process, as well as support to participants, during a time of changing life roles (Brookshire, 1997). Multipurpose groups encompass a variety of goals, such as language stimulation, social goals, emotional support, and carryover.

In addition to communicative gains, group treatment may be financially beneficial for PWA, in that the cost for one hour of treatment may be distributed across several clients, thus reducing the cost for each individual. Elman (1998) suggested that group treatment offered a cost-effective alternative for continuing services, when reductions in the intensity, frequency, and duration of treatment were the rule rather than the exception, due to trends in managed care. In addition, group treatment offers individuals with aphasia a realistic option for long-term rehabilitation. The costs associated with this form of therapy are comparable to other life-enhancing expenditures, such as a gym membership or continuing education classes (Beeson & Holland, 2007).

Although there is evidence for the effectiveness of both group therapy and individual therapy approaches, it is not clear what the effect of combining these approaches may be. There are studies comparing individual and group therapy but, to the best of the student's knowledge, there are no studies comparing individual, group and combination (group and individual) therapy for people with aphasia. Based on the current evidence, one might hypothesise that a combination of approaches may be more effective than each approach in itself.

In the Thales aphasia project, elaborated semantic feature analysis was the chosen treatment for word level therapy. The next section will describe in more detail semantic feature analysis.

1.8 Semantic Feature Analysis Treatment

1.8.1 Theoretical Basis of Semantic Feature Analysis Treatment

Semantic feature analysis (SFA) is a widely known semantic treatment for evaluating word retrieval impairments. As Leonard, Rochon and Laird (2008, p. 924) reported, semantic treatments are “meaning – based treatment” and the primary purpose of these treatments is to guide a PWA to activate concepts associated to words (Davis, 2007). Theoretically, SFA was based on the concept of spreading activation within the semantic system (Collins & Loftus, 1975). Specifically, it was proposed that the level of semantic processing is a network of semantic representations and links associated to other related representations. Semantic representations with many shared properties were thought to be linked more closely compared to representations with minimal or no shared properties. The presentation of strongly related to the target features results in spreading of activation that converges onto the target concept; which receives a higher level of activation compared to other similar concepts. The targeted concept then activates the phonological information associated to it, resulting in the target word production. Consequently, re – learning or learning a strategy of activating strongly associated features for naming a target is the mechanism underlying SFA (Hashimoto & Frome, 2011).

Ylvisaker and Szekeres (1985) were the first to introduce semantic feature analysis (SFA), as an organisation method for facilitating semantic network activation. The same year, Haarbauer - Krupa and colleagues (1985a) developed a treatment for helping individuals with traumatic brain injury to structure their search of semantic and episodic memory aiming to organise and retrieve information (Haarbauer-Krupa et al., 1985a). Later, in 1994, Massaro and Tompkins, who applied SFA to two individuals with traumatic brain injury, refined SFA by measuring the production of semantic features and descriptors (not naming).

As discussed by Massaro and Tompkins (1994), early descriptions of SFA did not include details regarding its administration (Haarbauer-Krupa, Henry, Szekeres, & Ylvisaker, 1985a; Haarbauer-Krupa, Moser, Smith, Sullivan, & Szekeres, 1985b).

According to the initial explanations of SFA, the approach was a “structured thinking procedure” for “thought organization and verbal expression” (Haarbauer-Krupa, Henry, et al., p. 343) in which the feature strategy was applied in a structured manner until the patient “could complete an analysis with minimal cueing” (Haarbauer-Krupa, Moser, et al., p. 304). This description suggests that one of the treatment aims was the relatively independent use of the feature generation strategy.

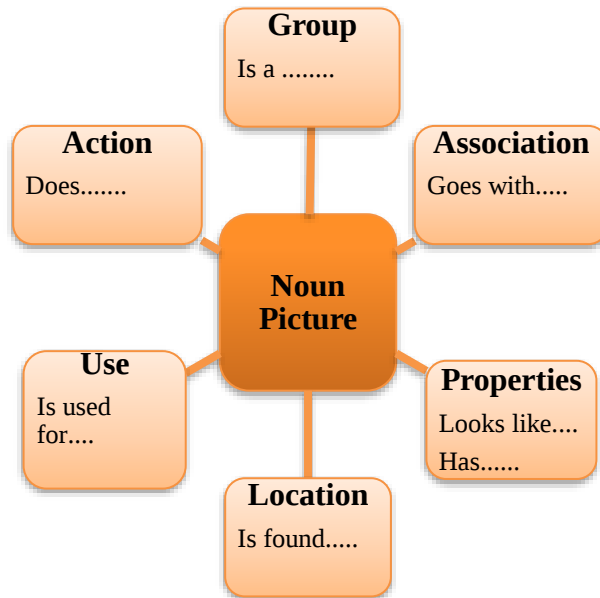
SFA as a treatment strategy aims to improve word retrieval, by strengthening the connections between the target word and its semantic network and thus facilitating picture naming (Boyle, 2004; Boyle & Coelho, 1995; Coelho, McHugh, & Boyle, 2000; Conley & Coelho, 2003; Haarbauer-Krupa et al., 1985; Lowell, Beeson, & Holland, 1995; Massaro & Tompkins, 1994). It is based on models of lexical retrieval, looking at the semantic system as a network of different concepts (Boyle, 2010). In particular, the meaning of a concept is derived from an organised structure of semantic features. Various concepts can be linked to a specific semantic feature, and/or a specific concept may include different semantic features. Semantic features are differentiated according to their degree of informativeness, with distinctive features being more informative than other features (Lombardi & Sartoni, 2007). For example, pear’s semantic features include <fruit >, <has a core>, <has skin>, <has seeds>, <grows on trees>, and <used for compote>. The information provided by its features differs, with some features providing more distinctive information (distinctive features) than others (common features). The feature <used for compote> distinguishes it from other fruits, like orange, whereas <has skin> does not distinguish it, because all fruits have skin.

The SFA treatment protocol involves employing a feature analysis chart that typically comprises the following semantic features for object naming: group, action, use, location, properties, and associations (Boyle, 2010) and for action naming: subject, purpose of action, part of body or tool used to carry out the action, description, usual location and associated objects or actions (Wambaugh & Ferguson, 2007) (see Figure 1.5). During SFA treatment, individuals with word retrieval difficulties are shown a picture to name and they are encouraged to generate the semantic features of the target

word by completing the feature analysis chart. If the treatment item is a noun e.g., “rabbit”: features that would be typically generated would include: group (“Rabbit is an animal”), properties (“It has long ears / fluffy tail”), function (“It can be a pet”), location (“Is found in a meadow”), action (“Hops”), and association (“Reminds me of Easter”). The completion of the feature categories is achieved by using systematic cueing techniques. For example, if the target word is “glass”, the cues might involve questions related to its use (e.g. What do you do with it?), its properties (e.g. What does it look like?), where it might be used, location, (e.g. Where do you find it?), what category - group it belongs to, and what might be associated with it (e.g. What other things are similar to it?). It is argued that generation of such semantic features works as a compensatory strategy to enhance activation of the target word via the processing of shared features, which enables the individual to find the target word. Persistent and systematic practice in producing semantic features in this way enables individuals to achieve more organized word retrieval without the deliberate use of compensatory strategies (Boyle, 2010).

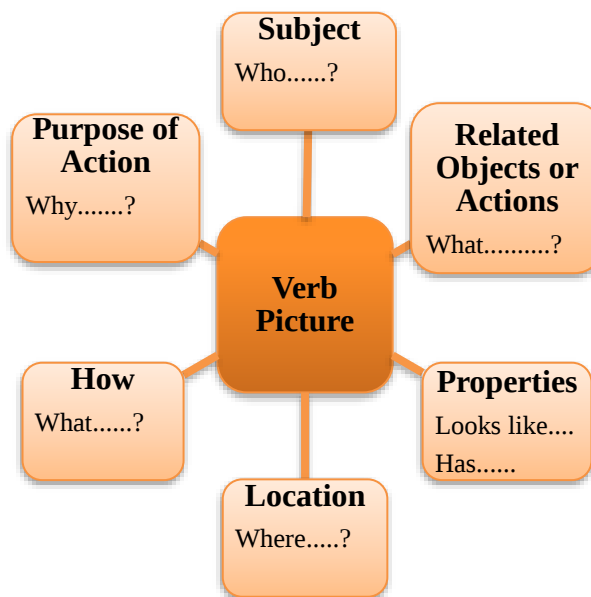
Figure 1.6: The feature analysis charts for nouns and verbs

a) Noun SFA



Boyle, 2004; Coelho et al., 2000

b) Verb SFA:



Wambaugh & Ferguson, 2007; Wambaugh et al., 2013

The evidence on the efficacy of SFA, based on single case studies, is strong. Two reviews have been previously conducted on SFA treatment. Boyle's (2010) report was the first and examined the efficacy of SFA. The review comprised seven studies where SFA was used for confrontation naming of nouns. Results were reported for 17 participants with aphasia, 16 of whom improved their ability to name pictured nouns. These participants had a variety of classic fluent and non-fluent aphasia syndromes. The review concluded that SFA treatments improve naming of treated items for most participants, regardless of whether they require participants to generate the features themselves or whether participants analyze features that have been generated by others (Boyle, 2010). Maddy, Capilouto and McComas (2014) conducted a systematic review on the same area, but excluded studies that involved verification rather than generation of features (Edmonds & Kiran, 2006; Kiran & Roberts, 2010). The review comprised 11 studies with 24 participants with aphasia. Seventeen of them had non-fluent aphasia and seven participants had fluent aphasia. Cohen's *d* was calculated and the majority of participants showed a small effect size. The percent of non-overlapping data was also calculated and a large treatment effect was present for the majority of participants. The review concluded that SFA is an effective intervention for improving confrontational naming of items trained in therapy; however, limited generalisation to untrained items and connected speech was reported in the majority of the included studies.

The next chapter comprises a systematic literature review of therapy studies using SFA for people with aphasia. This was felt necessary in order to extend the previous reviews (Boyle, 2010; Maddy et al., 2014) by including new research; evaluating the methodological quality of the existing studies; broadening the scope of the review by documenting the characteristics of SFA studies; and determining clinical efficacy.

In summary, naming deficits in aphasia are very common. They can arise from incorrect/incomplete activation of semantic or phonological information (Dell et. al., 2004; Schwartz et. al, 2000; Schwartz et. al, 2006). Different therapies based on semantic or phonological tasks have been developed and tested with people with aphasia. One

promising therapy, which focuses on semantic tasks, but also employs phonological tasks, including repetition, is Semantic Feature Analysis.

1.9 Aims of the Study

In this context, the present study aimed to:

1) Evaluate the efficacy of ESFA for people with aphasia on different domains of the WHO ICF framework, including quality of life, as compared to a delayed treatment control group.

Based on the literature, it was hypothesised that the therapy group will have improved language skills (Laska, 2011; Latimer, Dixon & Palmer, 2013; Lyon et al., 1997; Mattioli et al., 2013; Smania et al., 2006; Varley et al., 2016), while the delayed treatment control group will not. Given the dynamic nature of the previously described models of disability (WHO ICF and A-FROM) it was also hypothesised that ESFA, although specifically targeting the underlying language impairment, could perhaps lead to secondary gains in other levels of the models, such as communication and quality of life.

2) Compare and contrast the relative efficacy of ESFA therapy on different domains of the WHO ICF framework, including quality of life, as delivered in two different approaches - direct (individual) and indirect combination therapy (individual and group).

Based on the literature, it was hypothesised that direct therapy (individual therapy) will have greater benefits on participants' naming skills (Sarno, 1991; Cermak, 2011), while indirect therapy (combination therapy) will have greater benefits on functional communication, i.e. the ability of people to get their message across, using whatever means they can (Davis, 1986; Elman, 2001; Wilcox 1983). Combination therapy (individual and group therapy) may potentially have a greater effect on participants' well-being and life quality due to the reported psychosocial benefits of groups therapy (Ownsworth, Fleming, Shum, Kuipers, & Strong, 2008).

Chapter 2: A Systematic Literature Review of Semantic Feature Analysis Studies¹

This review aimed to comprehensively evaluate the current evidence on the efficacy of SFA by addressing the following research questions:

What is the methodological quality of studies evaluating the efficacy of SFA in aphasia therapy?

What are the characteristics of SFA aphasia therapy studies, in terms of i) type, dosage, duration and total amount of treatment, and ii) participant characteristics?

What are the results of SFA aphasia therapy studies, in terms of i) treatment outcomes, and ii) clinical efficacy as determined by effect sizes using Cohen's d or percent of non-overlapping data?

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher, Liberati, Tetzlaff, & Altman, 2009 & 2010) formed the basis of the conduct and reporting of this systematic review. PRISMA stems from an international collaboration formed to update the QUOROM Statement (Quality Of Reporting Of Meta-analyses). PRISMA provide an accepted, evidence-based minimum set of items for reporting in systematic reviews, which have been updated to address several conceptual and practical advances in the science of systematic reviews.

¹ This review as presented in this chapter (excluding section 2.7: summary), including some background information in the previous chapter, has been submitted for publication in Journal of Speech, Language and Hearing Research and is currently awaiting decision following amendments. Authors comprise Efstratiadou E.A., Papathanasiou I., Holland R., Archonti A., and Hilari K., hence 'we' is used in this chapter and there are references to 'the first author'.

2.1 Search Strategy and Eligibility Criteria

A systematic search of the literature was conducted to identify studies that investigated SFA as a primary intervention method for people with aphasia. Electronic searches of the following databases were conducted, with the last search in February 2017, using the EBSCOHOST platform: Academic Search Complete, CINAHL Plus with Full Text, E-Journals, MEDLINE with Full Text, PsycINFO, ERIC and the Aphasia Treatment website of the Academy of Neurologic Communication Disorders (<http://aphasiatx.arizona.edu/>).

The search strategy comprised the following terms:

1. Semantic feature analysis
2. Semantic cues
3. 1 or 2
4. Aphasia
5. Dysphasia
6. 4 or 5
7. Naming
8. Word finding difficult*
9. 7 or 8
10. 6 and 9
11. Therap*
12. Treat*
13. Intervention
14. 11 or 12 or 13
15. 3 and 10 and 14.

After removal of duplicate studies, material resulting from the searches was screened against the eligibility criteria. Studies were considered eligible if they were research reports and were published in English. Studies that combined SFA with other treatment approaches were excluded, when it was impossible to delineate specifically the effects of SFA. Where eligibility could not be assessed on the basis of the title and abstract alone, the full text was obtained.

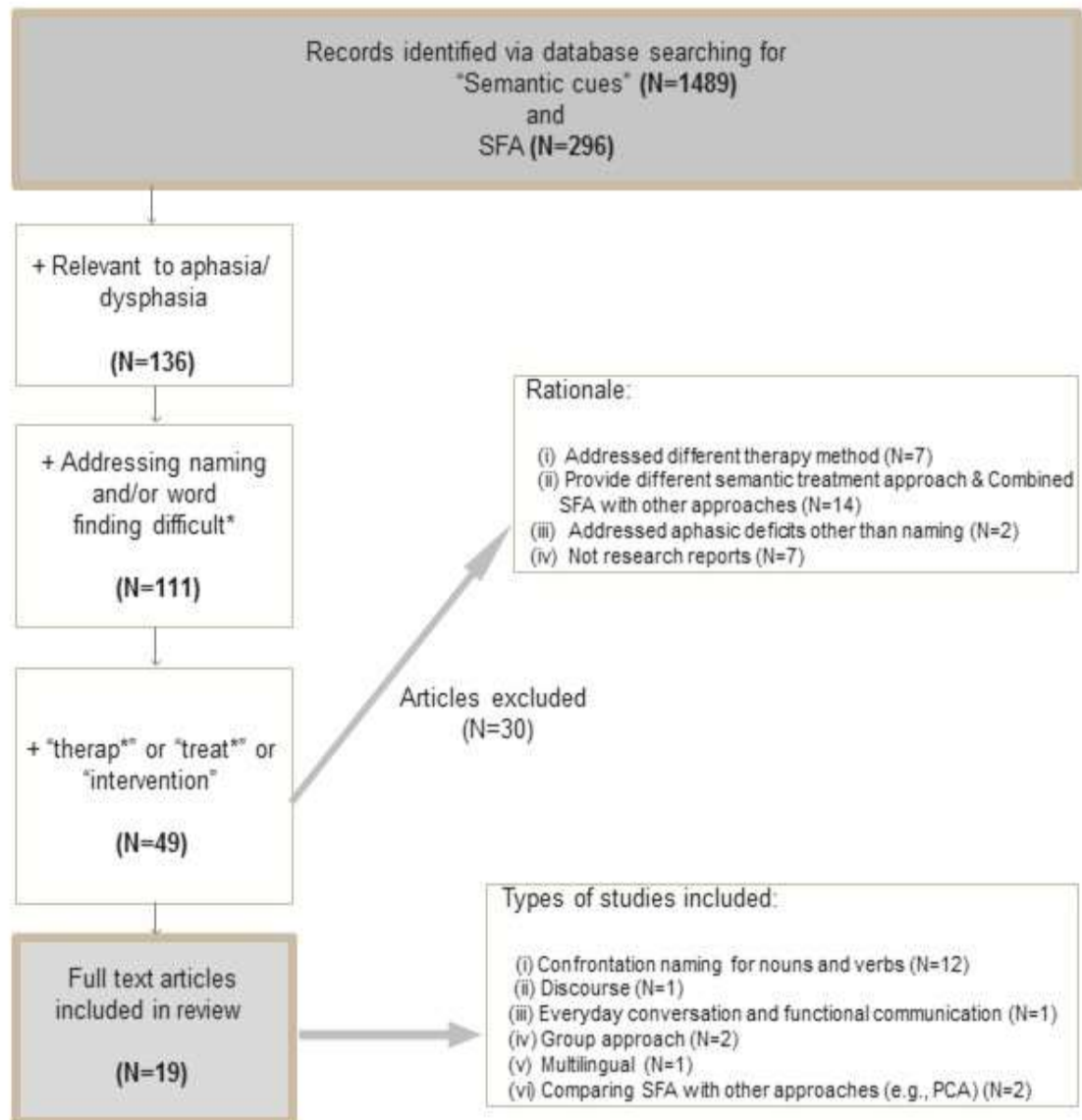
2.2 Study selection: Screening and data extraction

296 abstracts were found which mentioned Semantic Feature Analysis (SFA) in their abstract and 1489 abstracts that mentioned “semantic cues”. Of these, 136 were relevant to aphasia / dysphasia and 111 addressed “naming” and / or “word finding difficult*”. Of these, 49 were considered for this review as they also mentioned therapy / treatment / intervention. The full text was obtained for these 49 articles. Of these, seven were excluded as they used different therapy methods, like cueing hierarchy approach (Linebaugh, Shisler, & Lehner, 2005), multi cue computer program (Doesborgh et al., 2004; van Mourik, Verschaeve, Boon, Paquier, & van Harskamp, 1992), personal cueing in natural settings (Olsen, Freed, & Marshall, 2012), phonological components analysis (PCA) (Leonard, Rochon, & Laird, 2008), orthographic cueing (Leonard, Rochon, & Laird, 2004) and a different semantic approach which compared a phonological and orthographic approach (Lorenz & Ziegler, 2009). A further 14 articles were excluded, which mentioned semantic features but provided a different semantic treatment approach, such as semantic feature verification rather than generation, or combined SFA with other treatment approaches in the same therapy protocol, such as response elaboration training (RET), semantic priming, semantic judgment tasks, auditory concept feature and gesturing treatment (Antonucci, 2014a; Boo & Rose, 2011; Cameron, Wambaugh, Wright, & Nessler, 2006; Carragher, Conroy, Sage, & Wilkinson, 2012; Conley & Coelho, 2003; Edmonds & Kiran, 2006; Hashimoto, 2016; Kintz, Wright, & Fergadiotis, 2016; Kiran & Roberts, 2010; Law, Wong, Sung, & Hon, 2006; Lowell, Beeson, &

Holland, 1995; Raymer, Rodriguez, & Rothi, 2007; Wallace & Kimelman, 2013; Wambaugh, Mauszycki, Cameron, Wright, & Nessler, 2013). Moreover, one study was excluded, as comprehension SFA was evaluated (Munro & Siyambalapitiy, 2017). Lastly, an additional seven studies were excluded, as they were not research reports (Antonucci, 2014b; Bose & Buchman, 2007; Boyle, 2010; Durand & Asnaldo, 2014; Kiran & Bassetto, 2008; Maddy et al., 2014; van Hees, McMahon, Angwin, De Zubicaray, & Copland, 2014a) and one was excluded as it was not relevant to naming, instead it was treating oral reading (Kiran & Viswanathan, 2008). The remaining 19 articles were included in the review. The selection process of the articles is illustrated in figure 2.1.

The 19 studies covered six main areas: confrontation naming of nouns studies, confrontation naming of verbs studies, connected speech – discourse studies, multilingual study, group studies, and studies where SFA was compared with other approaches, like Phonological Components Analysis (PCA) (Hashimoto, 2012; van Hees, Angwin, McMahon, & Copland, 2013).

Figure 2.1: Identification process of articles from electronic databases



2.3 Critical Appraisal and Methodological Quality

We appraised the methodological quality of included studies and assigned levels of evidence as an indication of risk of bias. Two aphasia-specialist speech-language pathologists critically evaluated the included studies for their methodological quality. All studies were single case studies (N=19). The Single Case Experimental Design Scale (SCEDS) critical appraisal tool (Tate et al., 2008) was used to examine the quality of the studies. SCEDS is an 11-point scale evaluating the methodological quality of experimental single case studies. A perfectly designed and executed study would receive a summative score of 11 across eleven different criteria. A score of 1, per criterion, is given if the study adequately addresses the specified quality item and a score of 0 is given if the item is poorly addressed or not addressed at all. The eleven specified quality items are: (i) clinical history, (ii) target behaviors, (iii) design, (iv) baseline, (v) sampling behavior during treatment, (vi) raw data record, (vii) inter-rater reliability, (viii) independence of assessors, (ix) statistical analysis, (x) replication and (xi) generalisation. All included studies were evaluated with SCEDS by two raters. When disagreements between raters were present, an average score was calculated. The first author randomly selected six studies (31.58%) and re-calculated SCEDS scores to determine intra-rater reliability. Intra-rater reliability was ICC=1.0 (100% agreement). To reduce bias and ensure ratings were not dependent upon one another, re-scoring was completed two weeks after the initial scoring.

Level of evidence was also assigned to each of the studies. Level of evidence refers to the hierarchy of study designs based on the ability of the design to protect against bias. While there is no one universally accepted hierarchy, randomised control trials (RCTs) are considered to be the design least susceptible to bias, and various hierarchies follow from there through observational studies and non – experimental designs. Based on Scottish Intercollegiate Guidelines Network (<http://www.sign.ac.uk/pdf/sign118.pdf>, 2010) the hierarchy of levels of evidence is detailed in figure 2.2.

Figure 2.2: Levels of Evidence

Level	Description
Ia	Well - designed meta – analysis of >1 randomised controlled trial
Ib	Well – designed randomised controlled study
IIa	Well – designed controlled study without randomisation
IIb	Well – designed quasi – experimental study
III	Well – designed non – experimental studies, i.e., correlational and case studies
IV	Expert committee report, consensus conference, clinical experience of respected authorities

Phase of treatment was also considered for each study, using the coding of Robey and Schultz (1998 & 2004), which is a five – phase model: Phase 1 studies are pre – efficacy studies, where the goal is to determine if there is evidence to suggest that the treatment has therapeutic value. Phase 2 are pre- efficacy studies, where the goal is to develop, standardize, validate, and optimize procedures to explain why a therapy works and who are the ideal candidates. Phase 3 are efficacy studies, where treatment is tested for efficacy under ideal conditions. Phase 4 are effectiveness studies, where treatment is tested for effectiveness under ordinary conditions of use. Lastly, phase 5 are effectiveness studies exploring efficiency, cost-benefit, and patient reported outcomes such as satisfaction and quality of life.

2.4 Treatment outcomes and clinical efficacy

As well as describing the treatment outcomes of included studies, the clinical efficacy of SFA was determined by calculating effect sizes. Effect sizes could be calculated only in those studies that reported sufficient data. To calculate, it was necessary to determine the individual values for the pre- treatment and post-treatment phases for each set of trained items. Cohen's *d* statistic was used to calculate effect size as described by Busk and Serlin (1992). The magnitude of change in performance was determined according to the benchmarks for lexical retrieval studies described by Beeson and Robey (2006). The benchmarks were 4.0, 7.0, and 10.1 for small, medium, and large effect sizes respectively.

Where Cohen's *d* could not be calculated, the percent of non-overlapping data (PND) was calculated. PND is the most widely used method of calculating effect size in single case experimental designs (Gast, 2010; Schlosser, Lee, & Wendt, 2008;). PND is the percentage of phase B data points (the treatment phase) that do not overlap with phase A data points (baseline or no treatment). To determine the magnitude of effect, benchmarks put forth by Scruggs et al. (1987) were used. PND scores higher than 90% were considered to demonstrate a highly effective treatment, PND of 70–90% were interpreted as a moderate treatment outcome and PND scores of 50–70% were considered a questionable effect. PND scores less than 50% were interpreted as an ineffective intervention since performance during intervention had not affected behavior beyond baseline performance.

2.5 Results

2.5.1 Study selection

Nineteen studies were included in this systematic review. The studies cover six different research areas. Nine studies investigated SFA with confrontation naming of nouns (Boyle, 2004; Boyle & Coelho 1995; Coelho, McHugh & Boyle, 2000; Davis & Stanton, 2005; DeLong, Nessler, Wright, & Wambaugh, 2015; Hashimoto & Frome,

2011; Massaro & Tompkins, 1994; Mehta & Isaki, 2016; Rider, Wright, Marshall, & Page, 2008). Two studies examined SFA with confrontation naming of verbs (Wambaugh & Ferguson, 2007; Wambaugh, Mauszycki, & Wright, 2014) and a further two tested SFA with confrontation naming of nouns and verbs (Kristensson, Behrns, & Saldert, 2015; Marcotte & Ansaldo, 2010). Kristensson's study additionally explored everyday conversation and functional communication outcomes. Connected speech – discourse – was examined in one study (Peach & Reuter, 2010), group SFA was evaluated in two studies (Antonucci, 2009; Falconer & Antonucci, 2012), and multilingual SFA was tested in one study (Knoph, Lind, & Simonsen, 2015). Finally, two studies compared SFA with other approaches, like Phonological Components Analysis (PCA) (Hashimoto, 2012; van Hees et al., 2013). Before presenting the characteristics and details of the above studies their methodological quality will be considered.

2.5.2 Critical Appraisal and Methodological Quality

Across the 19 studies, scores on the SCEDS ranged from 8.0 to 11 with an average score of 9.66 out of 11 (Table 2.1). After SCEDS scoring, level of evidence was assigned for the studies. All studies were determined to be well – designed non – experimental / non – analytic studies and assigned a level III rating, except of Marcotte and Ansaldo (2010), which was classified as an observational control study.

Phase of treatment was obtained for all studies. Chronologically earlier studies, from 1994 until 2007 and Hashimoto's and Frome's study (2011), were Phase 1 studies (see Table 1), i.e., pre-efficacy studies (n=11), where the goal was to determine if there was evidence to suggest that the treatment had therapeutic value. All other studies, except for Rider et al., (2008) were Phase 2 pre-efficacy studies (n=7), where the goal was to develop, standardize, validate, and optimize procedures to explain why SFA worked and who were the ideal candidates. Rider and colleagues' study (2008) was a Phase 3 efficacy study, where treatment was tested for efficacy under ideal conditions. The prevalence of high SCEDS scores suggests the included studies were of good/adequate methodological quality, despite being pre-efficacy studies.

Table 2.1: Critical appraisal and methodological quality of studies (n=17) based on Single Case Experimental Design Scale (SCED))

Items of SCED Scale	Clinical History	Target Behaviours	Design	Baseline	Treatment Phase	Raw Data Record	Inter-Rater Reliability	Independence of Assessors	Statistical Analysis	Replication	Generalisation	Total Score of SCED Scale	Phase of treatment
1. Massaro & Tomkins, 1994	YES	YES	MBAB	YES	YES	YES	YES	YES	NO	YES	YES	10	Pre-efficacy 1
2. Boyle & Coelho, 1995	YES	YES	ABA	YES	YES	YES	YES	NO	NO	NO	YES	8	Pre-efficacy 1
3. Coelho et al., 2000	YES	YES	ABA	YES	YES	YES	YES	NO	NO	NO	YES	8	Pre-efficacy 1
4. Boyle, 2004	YES	YES	MBAB	YES	YES	YES	YES	YES	YES	YES	YES	11	Pre-efficacy 1
5. Davis & Stanton, 2005	YES	YES	MBAB	YES	YES	YES	YES	NO	NO	NO	YES	8	Pre-efficacy 1
6. Wambaugh & Ferguson, 2007	YES	YES	MBAB	YES	YES	YES	YES	YES	YES	YES	NO	10	Pre-efficacy 1
7. Rider et al., 2008	YES	YES	MBAB	YES	YES	YES	YES	YES	YES	YES	NO	10	Efficacy
8. Antonucci, 2009	YES	YES	ABA	YES	YES	YES	YES	YES	YES	YES	Partly	10.5	Pre-efficacy 2
9. Marcotte & Ansaldo, 2010	YES		AB		Not a single case study but an observation control study						No		Pre-efficacy 1
10. Peach & Reuter, 2010	YES	YES	Single case time series across behaviours	YES	YES	YES	YES	YES	YES	YES	Variable	10.5	Pre-efficacy 1

Items of SCED Scale	Clinical History	Target Behaviors	Design	Baseline	Treatment Phase	Raw Data Record	Inter-Rater Reliability	Independence of Assessors	Statistical Analysis	Replication	Generalization	Total Score of SCED Scale	Phase of treatment
11. Hashimoto & Frome, 2011	YES	YES	MBAB	YES	YES	YES	YES	YES	YES	YES	YES	11	Pre-efficacy 1
12. Falconer & Antonucci, 2012	YES	YES	ABA	YES	YES	YES	YES	NO	YES	YES	YES	9	Pre-efficacy 2
13. Hashimoto, 2012	YES	YES	MBAB	YES	YES	YES	YES	YES	YES	YES	Partly	10.5	Pre-efficacy 2
14. van Hees et al., 2013	YES	YES	ABA	YES	YES	YES	NO	NO	YES	YES	NO	8	Pre-efficacy 2
15. Wambaugh et al., 2014	YES	YES	MBAB	YES	YES	YES	YES	YES	YES	YES	NO	10	Pre-efficacy 2
16. Kristensson et al., 2015	YES	YES	MBAB	YES	YES	YES	YES	YES	YES	YES	NO	10	Pre-efficacy 1
17. DeLong et al., 2015	YES	YES	MBAB	YES	YES	YES	YES	YES	YES	YES	Variable	10.5	Pre-efficacy 1
18. Knoph et al., 2015	YES	YES	AB	YES	YES	YES	YES	NO	YES	YES	YES	10	Pre-efficacy 2
19. Mehta & Isaki, 2016	YES	YES	ABA	YES	YES	YES	NO	YES	YES	YES	NO	9	Pre-efficacy 2

SCED: Single Case Experimental Design

MBAB: Multiple baseline across behaviors study, involving multiple assessments pre- treatment, post-treatment and follow up

AB: Pre- / post- treatment study

ABA: Pre- / post- treatment / follow up study

2.5.3 Characteristics of studies:

2.5.3.1 Type and duration of treatment

Study and participant characteristics are shown in Tables 2.2 and 2.3. Table 2.2 details the number of participants, type of SFA treatment, dosage and duration of treatment and total amount of treatment expressed in minutes. A total of 47 participants have been treated in the included studies. Nine studies, with a total of 18 monolingual individuals, tested SFA in confrontation naming tasks of single nouns (Boyle, 2004; Boyle & Coelho 1995; Coelho et al., 2000; Davis & Stanton, 2005; DeLong et al., 2015; Hashimoto & Frome, 2011; Massaro & Tompkins, 1994; Mehta & Isaki, 2016; Rider et al., 2008). Treatment duration ranged from five to 12 weeks and treatment was delivered in two to three 60 minute sessions per week, with a total amount of treatment of 12 to 24 hours [mean (SD)= 18 (4.38)]. Two studies, with five monolingual participants, applied SFA in confrontation naming tasks that targeted single verbs (Wambaugh & Ferguson, 2007; Wambaugh et al., 2014). The treatment duration was four weeks and treatment was delivered in three 45 - 60 minutes' sessions per week. Two SFA studies combined confrontation naming tasks of single nouns and verbs (Kristensson et al., 2015; Marcotte & Ansaldo, 2010). In Marcotte and Ansaldo's (2010) study the treatment duration for the individual was three weeks and he had three 60 minutes' sessions per week resulting in nine hours of therapy in total. In Kristensson and colleagues' (2015) study the three participants received 20 hours of treatment delivered in 20 sessions lasting 60 minutes each for a period of five to six weeks. Discourse SFA was evaluated in three studies, one using an individual approach (Peach & Reuter, 2010) and two using a group approach (Antonucci, 2009; Falconer & Antonucci, 2012). Individual discourse SFA was evaluated with two participants, one monolingual and one bilingual (Peach & Reuter, 2010). Treatment was delivered in 50 minutes' sessions and lasted ten weeks, with a total amount of treatment of 11-12 hours. Group approach SFA was tested in two studies (Antonucci, 2009; Falconer & Antonucci, 2012), with seven monolingual participants, for seven weeks, with a small difference on the amount of hours in each study. In Antonucci (2009) each session ranged from 60 to 90 minutes and in Falconer and Antonucci (2012) from 90 - 120 minutes, resulting in a total amount of treatment of 1050 - 1470 minutes [mean (SD) = 1260 (296.98)]. Multilingual SFA was tested in one study (Knoph, Lind, & Simonsen, 2015), with one quadrilingual participant, for two and a half weeks, each session ranged from 45 to 55 minutes, resulting in a total amount of 1320 minutes. Lastly,

two studies compared SFA with PCA (Hashimoto & Frome, 2012; van Hees et al., 2013) in a total of 10 participants. In the Hashimoto & Frome (2012) study, two participants were seen twice weekly and had two 45-60 minute sessions on each of these two days for 15 to 25 weeks. In van Hees et al (2013) study, eight participants received three 45-90 minute sessions per week for four weeks. Total amount of treatment ranged from 540 minutes (Marcotte & Ansaldo, 2010) to 1500 minutes (Boyle, 2004) [mean (SD) = 1019.69 (337.17)].

2.5.3.2 Participant characteristics

Table 2.3 presents the demographic characteristics of the 47 participants from the 19 reviewed studies. Considerable heterogeneity was found across the participants in terms of age and time post onset. Age ranged from 24 to 80 years, with a mean (SD) age of 56.52 (13.01). Time post onset ranged from 4 to 384 months, with a mean (SD) of 62.58 (73.16) months. Twenty-five participants were men and twenty-two were women. Of the participants, 18 were described as non-fluent and 28 as fluent (one was not reported). Aphasia was due to a stroke in 40 individuals and to traumatic brain injury in four individuals (neuropathology for three individuals was not reported). Aphasia severity was reported or derived from the aphasia quotient (AQ) of the WAB in 14 studies. Three studies based aphasia severity on a different test and two did not report severity. One participant presented with very severe aphasia, three with severe, three with moderate to severe, 22 with moderate, three with mild to moderate, and 12 with mild aphasia. Aphasia type was not reported for six participants. Of the remaining, 11 had Broca's aphasia, 12 anomic, five Wernicke's, eight conduction, one global, one mixed and three transcortical motor aphasia.

Table 2.2: Study characteristics: number of participants, type of SFA treatment, dosage, duration and amount of treatment

Study	n	Type of SFA	Language	Treatment dosage and duration	Total amount of treatment (mins)
1. Massaro & Tompkins, 1994	2	Noun SFA	Monolingual	21 sessions	CNC
2. Boyle & Coelho, 1995	1	Noun SFA	Monolingual	3*60min sessions/wk 6 weeks	1080
3. Coelho et al., 2000	1	Noun SFA	Monolingual	3*60min sessions/wk 7 weeks	1260
4. Boyle, 2004	2	Noun SFA	Monolingual	3*50- 75 min sessions/wk 8 weeks	≈1500
5. Davis & Stanton, 2005	1	Noun SFA	Monolingual	2* 60 min sessions/wk 6 weeks	720
6. Wambaugh & Ferguson, 2007	1	Verb SFA	Monolingual	3*45 - 60 min sessions/wk 4 weeks	≈630
7. Rider et al., 2008	3	Noun SFA	Monolingual	2-3 * 60min sessions/wk 5 weeks or 80% naming accuracy across 2 sessions	≈750
8. Antonucci, 2009	3	Group Approach Discourse SFA	Monolingual	2*60 -90min sessions/wk 7 weeks	≈1050

9. Marcotte & Ansaldo, 2010	1	Nouns & Verb SFA	Monolingual	3*60min sessions/wk 3 weeks	540
				P1: 14 *50 min per sessions	
10. Peach and Reuter, 2010	2	Discourse SFA	Bilingual	10 weeks P2: 13*50 min per sessions 10 1/2 weeks	≈675
11. Hashimoto & Frome, 2011	1	Modified Noun SFA	Monolingual	2*60min sessions/wk 12 weeks	1440
12. Falconer & Antonucci, 2012	4	Group Approach Discourse SFA	Monolingual	2* 90 - 120 min sessions/wk 7 weeks & daily practice of homework	≈1470
13. Hashimoto, 2012	2	SFA vs PCA	Monolingual	2*45-60min sessions per day 4 sessions/wk until >80% naming accuracy across 3 sessions 2 – 7 1/2 weeks	≈1470
14. van Hees et al., 2013	8	SFA vs PCA	Monolingual	3* 45-90min sessions/wk 4 weeks	≈810
15. Wambaugh et al., 2014	4	Verb SFA	Monolingual	3*60min sessions/wk Until 90% accurate naming	720

Table 2.3: Participants' demographic and stroke and aphasia characteristics (N=51)

Study	n	Participant s	Age (years)	Gender	Etiology	TPO (months)	WAB AQ Aphasia Severity ^a	Aphasia Type	Fluency
1. Massaro & Tompkins, 1994	2	P1	24	M	TBI	60	NR	Broca	Non – Fluent
		P2	28	F	TBI	144	NR	NR	Non -Fluent
2. Boyle &Coelho, 1995	1	P1	57	M	L CVA	65	82 Mild	Broca	Non - Fluent
3. Coelho et al., 2000	1	P1	52	M	TBI	17	56.6 Moderate	NR	Fluent
4. Boyle, 2004	2	P1	70	M	L CVA	15	90.6 Mild	Anomic	Fluent
		P2	80	M	LCVA	14	61.2 Moderate	Wernicke	Fluent
5. Davis & Stanton, 2005	1	P1	59	F	CVA	4	102 ^b Moderate	NR	Fluent
6. Wambaugh & Ferguson, 2007	1	P1	74	F	L CVA	50	67.7 Moderate	Anomic	Non - Fluent
7. Rider et al., 2008	3	P1	73	M	L CVA	26	74.6 Moderate - Mild	Transcortical Motor	Non – Fluent
		P2	55	F	L CVA	45	76.5 Mild	Transcortical Motor	Non – Fluent
		P3	62	M	L CVA	126	66 Moderate	Broca	Non - Fluent
8. Antonucci, 2009	3	P1	NR	M	NR	NR	NR	NR	NR
		P2	53	M	NR	18	63 Moderate	Conduction	Fluent
		P3	59	F	NR	16	90.2 Mild	NR	Fluent
9. Marcotte & Ansaldo, 2010	1	P1	66	M	CVA	84	Severe	Broca	Non – Fluent
10. Peach & Reuter, 2010	2	P1	77	F	L CVA	4	90.2 Mild	Anomic	Fluent
		P2	62	F	L CVA	14	70.3 Moderate	Anomic	Fluent
11. Hashimoto & Frome, 2011	1	P1	72	F	CVA	NR	35 Severe	Broca	Non -Fluent

12. Falconer & Antonucci, 2012	4	P1	35	M	M CVA	72	69.6 Moderate	Conduction	Fluent
		P2	55	M	L CVA	156	61 Moderate	Conduction	Fluent
		P3	31	M	TBI	96	34 Severe	Broca	Non –Fluent
		P4	62	F	M CVA	25	52.4 Moderate	Transcortical Motor	Non -Fluent
13. Hashimoto, 2012	2	P1	66	F	L CVA	60	49.5 Severe - Moderate	Wernicke	Non – Fluent
		P2	33	F	L CVA	18	57.5 Moderate	Broca	Fluent
14. van Hees et al., 2013	8	P1	60	F	L CVA	38	77.2 Mild – Moderate	Conduction	Fluent
		P2	60	M	L CVA	57	87.4 Mild	Anomic	Fluent
		P3	41	F	L CVA	170	92 Mild	Anomic	Fluent
		P4	52	F	L CVA	55	86.4 Mild	Conduction	Fluent
		P5	56	F	L CVA	25	57.3 Moderate	Anomic	Fluent
		P6	48	F	L CVA	17	81.7 Mild	Anomic	Fluent
		P7	69	M	L CVA	36	73.4 Moderate	Anomic	Fluent
		P8	65	M	L CVA	20	82.9 Mild	Anomic	Fluent
15. Wambaugh et al., 2014	4	P1	48	F	L MCA	276	77.4 Mild	Conduction	Fluent
		P2	53	M	L PCA	66	83.4 Mild	Anomic	Fluent
		P3	55	M	L CVA	79	53 Moderate	Broca	Non – Fluent
		P4	60	M	R MCA L MCA	21	66.9 Moderate	Broca	Non - Fluent
16. Kristensson et al., 2015	3	P1	71	M	L PCA	36	Moderate – Severe	Wernicke	Fluent
		P2	54	F	L BG	60	Moderate – Severe	Mixed	Non- Fluent
		P3	64	M	L MCA	24	Mild – Moderate	Broca	Non – Fluent
17. DeLong et al., 2015	5	P1	62	F	L CVA	11	64.5 Moderate	Conduction	Fluent
		P2	54	M	L MCA	30	58.3 Moderate	Wernicke	Fluent
		P3	30	M	L MCA	23	66 Moderate	Broca	Fluent

18. Knoph et al., 2015		P4	53	F	L MCA	384	78.4 Moderate	Anomic	Fluent
		P5	65	F	L MCA	12	18 Very Severe	Global	Non – Fluent
	1	P1	59	F	L NR	7	Moderate ^c	NR	Non – Fluent
19. Mehta & Isaki, 2016		P1	58	M	L CVA	108	53 Moderate	Wernicke	Fluent
	2	P2	58	M	L CVA	132	60.2 Moderate	Conduction	Fluent

a: Aphasia severity based on Western Aphasia Battery-Revised (Kertesz, 2007) Aphasia Quotient. Retrieved October 1, 2015, from <http://www.pearsonclinical.com/language/products/100000194/western-aphasia-batteryrevised.html>

b: Based on Aphasia Diagnostic Profiles score (Helm-Estabrooks, 1992)

c: Based on Bilingual Aphasia Test (Paradis, Libben, & Hummel, 1987)

NR: not reported; R: Right hemisphere; L: left hemisphere; TPO: Time Post Onset; MCA: Middle Cerebral Artery; CVA: Cerebral Vascular Accident; PCA: Posterior Cerebral Artery; BG: Basal Ganglia

2.5.3.3 Synthesis of results

2.5.3.3.1 Treatment outcomes

The main treatment outcomes of the reviewed studies are summarized in Table 2.4. Improvement in naming of trained items was found for 37 participants (78.72%). Maintenance of naming of the trained items was reported for 28 participants (62.22%). Generalisation effects ranged from negligible (e.g., Rider et al., 2008) to strong (Boyle, 2004). The percentage of generalisation to untrained items for all studies was small (31.82%).

In relation to aphasia type and the outcome of SFA therapy, we looked firstly at improvement on the trained items. Nine of the 11 (81.82%) participants with Broca's aphasia, eight of the 12 anomic participants (66.66 %), four of the five (80%) individuals with Wernicke's aphasia, and all eight with conduction aphasia and three with transcortical motor aphasia (100%) showed improvement on naming of trained items. Negative outcomes were found for the two participants with global and mixed aphasia. In terms of maintenance, the findings were positive for seven (63.64%) participants with Broca's aphasia and all those with conduction and transcortical motor aphasia (100%), whereas only two (40%) of participants with Wernicke's aphasia, four (33.33 %) of the anomic participants and none of the two individuals with global or mixed aphasia showed a maintenance effect. In terms of generalisation to untreated items, it was mostly the individuals with Broca's aphasia that showed positive gains (45.45 %). All other aphasia type participants showed minimal gains on generalisation to untreated items. Specifically, gains were reported for 25% of the participants with conduction or Wernicke's aphasia, 16.67 % of those with anomic aphasia and 33.33% of the individuals with transcortical motor aphasia.

Table 2.4: Summary of treatment outcomes

Study	n	Treated items improved?	Maintenance	Generalisation to untreated items?
1. Massaro & Tompkins, 1994	2	YES	YES	YES
		YES	YES	YES
2. Boyle & Coelho 1995	1	YES	YES	YES
3. Coelho et al., 2000	1	YES	YES	YES
4. Boyle, 2004	2	YES	YES	YES
		YES	Unavailable	YES
5. Davis & Stanton, 2005	1	YES	YES	YES
6. Wambaugh & Ferguson, 2007	1	YES	YES	NO
7. Rider et al., 2008	3	YES	YES	NO
		YES	YES	NO
		YES	NO	NO
8. Antonucci, 2009	3	YES	YES	YES
		YES	YES	NO
		NO	Unavailable	Unavailable
9. Marcotte & Ansaldo, 2010	1	YES		
10. Peach and Reuter, 2010	2	YES	NO	Variable
		YES	NO	Variable
11. Hashimoto & Frome, 2011	1	YES	YES	YES
12. Falconer & Antonucci, 2012	4	YES	YES	YES
		YES	YES	YES
		YES	YES	YES
		YES	YES	YES
13. Hashimoto, 2012	2	YES	YES	NO
		YES	YES	YES
14. van Hees et al., 2013	8	YES	YES	NO
		YES	NO	NO
		YES	YES	NO
		YES	YES	NO
		NO	NO	NO
		NO	NO	NO
		NO	NO	NO
		NO	NO	NO

15. Wambaugh et al., 2014	4	YES	YES	NO
		YES	YES	NO
		YES	YES	NO
		NO	NO	NO
16. Kristensson et al. 2015	3	NO	NO	NO
		NO	NO	NO
		NO	NO	NO
17. DeLong et al., 2015	5	YES	YES	NO
		YES	NO	NO
		YES	YES	NO
		YES	NO	NO
		NO	NO	NO
18. Knoph et al., 2015	1	YES		NO
19. Mehta & Isaki, 2016	2	YES	YES	
		YES	YES	
Total	47	YES n=37 (78.72%) NO n=10 (21.28%)	YES n=28 (62.22%) NO n=15 (33.33%) Unavailable n=2 (4.44%)	YES n=14 (31.82%) NO n=27 (61.36%) Variable n=2 (4.54%) Unavailable n=1 (2.27%)

All studies assessed post - therapy gains immediately after treatment ended. The number of assessments and the timing of follow-up assessments varied (table 2.5). Overall, two studies assessed gains only once post-therapy (Knoph, Lind, & Simonsen, 2015; Marcotte & Ansaldo, 2010) and 17 included follow-up/maintenance assessments. Five studies assessed maintenance at an early time point: two weeks after therapy (DeLong et al., 2015; Massaro & Tompkins, 1994; van Hees et al., 2013; Wambaugh et al., 2014; Wambaugh & Ferguson, 2007), with the studies of Wambaugh et al. (2007 & 2014) and DeLong et al. (2015) assessing maintenance again six weeks later. Four studies assessed maintenance gains one month after completing therapy (Boyle, 2004; Boyle & Coelho, 1995; Coelho et al., 2000; Rider et al., 2008), with Boyle & Coelho (1995) and Coelho et al. (2000) assessing maintenance again two months after treatment ended. Five studies did not assess maintenance gains until six weeks after the end of treatment (Antonucci, 2009; Davis & Stanton, 2005; Falconer & Antonucci, 2012; Hashimoto, 2011; Hashimoto, 2012). Three studies assessed maintenance gains 2 - 4.5 months after treatment ended (Kristensson et al., 2015; Mehta & Isaki, 2016; Peach & Reuter, 2010).

Davis and Stanton (2005) was the only study to assess maintenance of gains at multiple time points and in the longer term: six, twelve, eighteen weeks and one year after therapy ceased.

Table 2.5: Time of Assessments after Therapy

Study	Number of Assessments	Time of Assessment after Therapy				
1. Massaro & Tompkins, 1994	2	Immediately after therapy	2 weeks			
2. Boyle & Coelho 1995	3	Immediately after therapy	1 month	2 months		
3. Coelho et al., 2000	3	Immediately after therapy	1 month	2 months		
4. Boyle, 2004	2	Immediately after therapy	1 month			
5. Davis & Stanton, 2005	5	Immediately after therapy	6 weeks	12 weeks	18 weeks	1 year
6. Wambaugh & Ferguson, 2007	3	Immediately after therapy	2 weeks	6 weeks		
7. Rider et al., 2008	2	Immediately after therapy	4 weeks			
8. Antonucci, 2009	2	Immediately after therapy	6 weeks			
9. Marcotte & Ansaldo, 2010	1	Immediately after therapy				
10. Peach and Reuter, 2010	2	Immediately after therapy	4 ½ months			
11. Hashimoto & Frome, 2011	2	Immediately after therapy	6 weeks			
12. Falconer & Antonucci, 2012	2	Immediately after therapy	6 weeks			
13. Hashimoto, 2012	2	Immediately after	6 weeks			

		therapy				
14. van Hees et al., 2013	2	Immediately after therapy	2-3 weeks			
15. Wambaugh et al., 2014	3	Immediately after therapy	2 weeks	6 weeks		
16. Kristensson et al. 2015	2	Immediately after therapy	10-12 weeks			
17. DeLong et al., 2015	3	Immediately after therapy	2 weeks	6 weeks		
18. Knoph et al., 2015	1	Immediately after therapy				
19. Mehta & Isaki, 2016	2	Immediately after therapy	8 weeks			

2.5.3.4 Clinical efficacy

Effect sizes for treatment outcomes were reported in eleven studies (Antonucci, 2009; DeLong et al., 2015; Falconer & Antonucci, 2012; Hashimoto & Frome, 2011; Hashimoto, 2012; Knoph et al., 2015; Kristensson et al., 2015; Peach & Reuter, 2010; Rider et al., 2008; van Hees et al., 2013; Wambaugh et al., 2014;). Calculation could not be performed for six studies (Boyle & Coelho, 1995; Coelho et al., 2000; Davis & Stanton, 2005; Marcotte & Ansaldo, 2010; Massaro & Tompkins, 1994; Mehta & Isaki, 2016).

The first author of the review calculated effect sizes for two studies (n=2) (Boyle, 2004; Wambaugh & Ferguson; 2007), as well as average effect sizes for six studies (n=20) (Antonucci, 2009; DeLong et al., 2015; Hashimoto & Frome, 2011; Kristensson et al., 2015; Rider et al., 2008; Wambaugh et al., 2014) (Table 2.6). Average effect sizes were calculated when data were collected and reported on two or more trials at one-time point. Large effect sizes were present for four participants ($d = 10.07 - 18.76$). Medium effect sizes were present for four participants ($d = 7.00 - 8.66$). Small effect sizes were present for eight participants ($d = 4.14 - 6.87$). For 13 participants, effect sizes were negligible. Effect size and PND could not be calculated for five participants from the

studies of Marcotte and Ansaldo (2010), Mehta and Isaki (2016) and one participant from DeLong et al. (2015) and Antonucci (2009) studies.

PND was calculated for six studies (Boyle, 2004; Boyle & Coelho, 1995; Coelho et al., 2000; Davis & Stanton, 2005; Massaro & Tompkins, 1994; Peach & Reuter, 2010), for seven participants for whom effect sizes could not be calculated. A large treatment effect (PND > 90%) was evident for six participants and a moderate treatment effect for one participant (PND = 85%). When examining clinical efficacy using PND, treatment was highly effective for the majority of participants. None of the participants had PND scores consistent with ineffective treatment.

Table 2.6: Clinical Efficacy: effect sizes and percent of non-overlapping data

Study	Participants	Cohen's d	PND	Magnitude of effect
1. Massaro & Tompkins, 1994	P1 P2	CNC CNC	100% 100%	Highly effective Highly effective
2. Boyle & Coelho 1995	P1	CNC	100%	Highly effective
3. Coelho et al., 2000	P1	CNC	100%	Highly effective
4. Boyle, 2004	P1 P2	18.48 ^a CNC	 100%	Large effect Highly effective
5. Davis & Stanton, 2005	P1	CNC	91.67%	Highly effective
36. Wambaugh & Ferguson, 2007	P1	6.35 ^a		Small effect
7. Rider et al., 2008	P1 P2 P3	3.86 ^b 5.54 ^b 2.97 ^b		Less than small effect Small effect Less than small effect
8. Antonucci, 2009	P1 P2 P3	CNC ns 2.05 ^b	CNC CNC CNC	Less than small effect
9. Marcotte & Ansaldo, 2010	P1	CNC	CNC	- -
10. Peach & Reuter, 2010	P1 P2	1.79	85%	Less than small effect Moderate effective
11. Hashimoto & Frome, 2011	P1	10.56 ^b		Large effect
12. Falconer & Antonucci, 2012	P1 P2 P3 P4	3.44 4.16 0.03 1.28		Less than small effect Small effect Less than small effect Less than small effect
13. Hashimoto, 2012	P1 P2	7.11 7		Medium effect Medium effect
14. van Hees et al., 2013	P1 P2 P3 P4 P5 P6 P7 P8	5.29 ns 4.14 8.66 ns ns ns ns		Small effect - Small effect Medium effect - - - -
15. Wambaugh et al., 2014	P1 P2 P3 P4	6.87 ^b 13.14 ^b 1.58 ^b 8.53 ^b		Small effect Large effect Less than small effect Medium effect
16. Kristensson et al., 2015	P1 P2 P3	1.06 ^b 0.66 ^b 0.64 ^b		Less than small effect Less than small effect Less than small effect
17. DeLong et al., 2015	P1	3.03 ^b		Less than small effect

	P2	2.20 ^b		Less than small effect
	P3	4.68 ^b		Small effect
	P4	6.66 ^b		Small effect
	P5	CNC	CNC	-
18. Knoph et al., 2015	P1	10.07		Large effect
19. Mehta & Isaki, 2016	P1	CNC	CNC	-
	P2	CNC	CNC	-

PND: percent of non-overlapping data; CNC: Cannot calculate, ^a: Calculated by first author,

^b: Average calculation by first author, ns: no substantial change

2.6 Discussion

The purpose of this review was to evaluate the quality of SFA therapy studies in aphasia; detail their characteristics and synthesize their results. We reviewed 19 studies reporting on 47 persons with aphasia. Improvement in naming of trained items was found for 37 participants (78.72%). Thus, SFA improved treated items for the majority of participants. Yet, effect size calculations indicated that there was a small or less than small treatment effect for a substantial proportion of participants (21/37, 56.76%). Moreover, although findings suggest that treatment was effective for improving naming of trained items, limited generalisation to untrained items and connected speech was reported (31.82%).

Maintenance of the trained items post therapy was reported for 28 participants (62.22%). Maintenance of therapy gains can be affected by factors like the timing of assessment, treatment dosage and duration (Boyle, 2010). Timing of assessment for maintenance effects varied (see Table 2.5). This variation may affect results, as when the evaluation is closer to the end of the intervention, maintenance of gains is more likely than when maintenance is assessed after a longer period. Looking at short-term maintenance, from the 19 studies, short - term post – therapy gains (two weeks) were reported in only five studies (DeLong et al., 2015; Massaro & Tompkins, 1994; Wambaugh et al., 2014; Wambaugh & Ferguson; 2007; van Hees et al., 2013). Eleven of the 20 participants (55%) in these studies showed a maintenance effect. If we consider longer-term post – therapy gains, six studies looked at two months or more post therapy, with 5 of 10 participants (50 %) showing maintenance of treatment gains (Boyle & Coelho, 1995; Coelho et al., 2000; Davis & Stanton, 2005; Kristensson et al., 2015; Mehta & Isaki, 2016; Peach & Reuter, 2010). Though the results seem to confirm that closer to the end of therapy gains are more likely to be maintained, we need to interpret this with caution as the number of participants assessed in the longer term (≥ 2 months) is small.

Results of generalisation to untreated items ranged from strong (e.g., Boyle, 2004) to negligible (e.g., Rider et al., 2008; Wambaugh et al., 2014; Wambaugh & Ferguson, 2007). Positive generalisation outcomes were evident for 31.82% of participants. It is argued that generalisation may be related to the underlying mechanism of how SFA

works. That is, if SFA has a semantic network repair function, then untreated items that belong to the same semantic category as trained items will indirectly benefit from treatment. Items that lie outside of the semantic network would not be likely to benefit. However, if SFA functions as a self-employed “semantic cueing strategy”, as Lowell and colleagues (1995) suggested, it would be expected that semantically related and unrelated items would improve when the strategy is implemented successfully. In this review, it has not been possible to evaluate this hypothesis as limited information was provided in most studies on the nature of generalisation. However, Boyle (2004) performed a post hoc analysis of categorical membership of treated and untreated experimental stimuli and found that generalisation occurred to untreated items that were not members of the same categories as treated items. Generalisation to unrelated items suggested that SFA functioned as a mediating strategy for naming those items.

Generalisation to untreated items in naming treatment studies has been questioned on the grounds of methodological issues (Howard, 2000; Nickels, 2002). Howard questioned whether the results of generalisation to untreated items could have been the effect of repeated exposure to generalisation probes throughout the study rather than true generalisation to untreated items. In his study, he investigated the effect of generalisation probes by dividing the generalisation probes into two sets. The first set of probes was presented only twice, once before treatment and once immediately after treatment ended, thus limiting their exposure. The second probe set was repeatedly presented during the treatment period at the beginning of each treatment session. It was found that people’s ability to successfully name the probe set that was repeatedly presented to them during therapy was greater than compared to those with limited exposure. Going a step further, Nickels (2002) conducted a case study to test Howard’s hypothesis. She instructed a man with aphasia to independently attempt to name a set of pictures. The individual practiced daily at his home and no feedback was given on his performance. After six days of practicing, his naming ability showed improvement and that improvement was maintained for six weeks, despite no further exposure to the pictures. Improvement was not generalised to written naming of those items or to spoken naming of unpracticed items. Nickels argued that the data supported Howard’s suggestion that repeated attempts to name pictures without feedback, like probes, can improve naming ability.

Given these data, reports of generalisation to untreated items where probes for generalisation to untreated items were used frequently during the treatment period must be questioned. Wambaugh and colleagues (2007 & 2014) tested this in their studies. In particular, in their 2007 study, four lists of items were used. List one and two were used as training items. Lists three and four were used for assessing the effects of generalisation to items with repeated and limited exposure. Specifically, list three was probed repeatedly along with training lists one and two. List four, was a “limited exposure” list, and was probed only once during the baseline phase and once again at the completion of treatment. The value of list four was that it permitted comparison of potential generalisation effects with the repeated probe list three. Results indicated that a trend of improved, but unstable, accuracy was noted for list three during training of list one, which continued during training of list two. During the true baseline phase, accuracy levels for list three ranged from 30% to 40% correct, with an average of 33% as correct. In the final three probes of the second treatment phase, list three accuracy levels increased and averaged at 50% correct. Importantly, however, as illustrated by the follow-up data, the changes in naming accuracy for list three were not lasting, whereas the changes in lists one and two remained. Minor changes were noted in responses to list four, which was probed only pre- and post-treatment. The lack of change in accuracy of production for list four items is consistent with Howard’s and Nickels finding. Wambaugh and colleagues (2007) suggested that repeated exposure during probing played a role in improved naming of list three items, but only for a short period of time and that improvement was maintained for the treated lists only (lists one and two). Thus, Wambaugh and colleagues (2007) concluded that exposure alone was not likely to significantly affect treatment gains, particularly longer-term.

Reports of generalisation to untreated items are more reliable from studies with limited generalisation probing, like Massaro and Tompkins (1994), Rider et al.’s (2008), Marcotte and Ansaldo (2010). The results from two of these three investigations (Marcotte & Ansaldo, 2010; Rider et al., 2008) corroborated the results from Howard (2000). They too did not find generalisation to untreated items. Only Massaro and Tompkins (1994) demonstrated a positive generalisation outcome to untreated items.

One study reported on a multilingual participant (Knoph et al., 2015) and found naming improvement in the untreated languages. Similar findings have been reported in prior studies of SFA in bilingual speakers (Edmonds & Kiran, 2006; Kiran & Roberts, 2010), with cross-linguistic transfer in some conditions for some participants. It has been suggested that cross-linguistic transfer is difficult to achieve (Ansaldi & Saidi, 2014; Farooqi - Shah et al., 2010). Yet, Knoph and colleagues (2015) hypothesized that the semantic nature of SFA therapy would lead to cross -linguistic transfer, and their results partly supported their hypothesis.

Although all studies focus on treating word finding difficulties in aphasia, pulling their results together is challenging due to the expected heterogeneity of various study components. A variety of aphasia types has been evaluated. Individuals with Broca's, Wernicke's, anomic, conduction, global, and transcortical motor aphasia syndromes have been included. Dividing participants to the broad categories of fluent and non – fluent aphasia, people with fluent aphasia are the most represented subtype in the reviewed studies (28/47, 58.57%). In terms of aphasia severity, the main body of the participants (78.72%) had mild (n=12), mild-moderate (n=3), or moderate (n=22) aphasia. Overall, results suggested that SFA as a treatment for word finding difficulties may be more effective for persons with fluent and moderate or mild aphasia (Antonucci, 2009; Boyle, 2004; Coelho et al., 2000; Hashimoto, 2012) compared to those with non – fluent and more severe aphasia (Hashimoto & Frome, 2011; Kristensson et al., 2015; Marcotte & Ansaldi, 2010). However, Boyle (2010) in a review of SFA treatments for nouns found that participants with severe aphasia also had positive responses. Lowell et al. (1995) suggested that aphasia severity and poor non-verbal cognitive skills were determining factors for participants who did not show improvement post therapy. Wambaugh and colleagues (2013) also suggested that different profiles of language, memory, and cognition might be associated with different responses to SFA. Further research with large numbers of participants is necessary in order to begin to unravel the impact of different aphasic profiles and severities on the efficacy of SFA.

Another important consideration is that treatments, which are called SFA, are not always the same in terms of their treatment protocols (Appendix A). Many studies

changed the traditional SFA protocol in various ways, such as modifications to the semantic feature categories (Mehta & Isaki, 2016; Wambaugh et al., 2014; Wambaugh & Ferguson, 2007), eliciting fewer features (Hashimoto & Frome, 2011; Mehta & Isaki, 2016), writing the features in addition to or instead of saying them (Hashimoto & Frome, 2011), following different treatment stages (Davis & Stanton, 2005), and adding new factors, such as independent homework (Falconer & Antonucci, 2012). This variability again makes it difficult to determine which aspects of SFA were most effective.

Different treatment outcomes could also be due to different treatment durations, dosages and total amount of treatment. Therefore, another limiting factor is the lack of a standardized dosage and treatment duration across studies. Some studies, like Hashimoto and Frome (2011) reported longer treatment sessions over a shorter duration. Across the studies reviewed, duration of treatment varied from two and a half weeks to twelve weeks [mean (SD) = 6.26 (2.46)]. Treatment sessions per week also varied from two to four sessions [mean (SD) = 2.72 (0.58)], and duration of sessions varied from 45 minutes to 90-120 minutes [mean (SD) = 62.19 (13.03)]. The most common duration per session was one hour (identified in eight different studies). It may be that total amount of treatment may relate to treatment outcomes. The findings of this review partly support this finding. There were seven studies with low amount of treatment, i.e. 540-720 minutes (Davis & Stanton, 2005; Marcotte & Ansaldo, 2010; Mehta & Isaki, 2016; Peach & Reuter, 2010; Rider et al., 2008; Wambaugh et al., 2007 & 2014). Fourteen of the 15 participants in these studies made gains in naming post-therapy, nine maintained these gains and three generalised to untreated items. In the six studies with high overall treatment amount (1260-1470 minutes), 11 of 11 participants made gains post-therapy, and 9 of 10 maintained these gains and generalised to untreated items (Boyle, 2004; Coelho et al., 2000; Falconer & Antonucci, 2012; Hashimoto & Frome, 2011; Hashimoto, 2012).

Despite the complicating factors of variability of treatment procedures, dosage, duration and changes to the traditional SFA protocol, this systematic review of SFA studies suggests that SFA is an effective intervention that can elicit positive therapy outcomes. Synthesizing the findings of 19 single case and case series studies suggests

that SFA is effective in improving treated items and has a small effect on generalisation to untrained items. In summary, the evidence-base for SFA as a therapeutic intervention is growing, but further research with larger numbers of participants is warranted to examine differential gains across aphasia types and explore generalisation to untreated items and longer term maintenance with greater confidence.

2.7 Summary

Literature findings suggest that SFA is an effective intervention, with positive outcomes despite the: a) variability of treatment procedures, dosage, duration and changes to the traditional SFA protocol; b) heterogeneity of participants and time post onset. Based on the above promising findings, this PhD project targeted to provide more evidence on the efficacy of Semantic Feature Analysis and address some of the needs for further research identified in the review. In particular, the present study uses a bigger sample of people with aphasia and follows a control group design, which can provide higher level of evidence than single case studies and case series. Moreover, the traditional SFA protocol as described by Boyle (1995 & 2004) is used, but at the end of the typical SFA procedure of word retrieval, the features are elaborated into a sentence (Elaborated Semantic Feature Analysis (ESFA) (Papathanasiou et al, 2006). Additionally, new evidence is offered to the research body by testing the efficacy of SFA in different therapy approaches (individual and group).

Chapter 3: Methods

This chapter describes the study methodology and the context in which the study took place. It also details the therapy offered.

Study methodology

3.1 Study design and change from original protocol

The main aim of the original Thales SLT stream was to compare the relative efficacy of ESFA, delivered in three different approaches - direct (individual), indirect (group) and combination therapy (individual and group), tapping on different domains of the WHO ICF framework. The study design was a randomised, parallel group, single-blinded trial. Randomisation was based on recruitment order (see 3.5 below) and the first group of participants was allocated to individual therapy. The second group was planned for group therapy. However, as participants in this second group received information on the project, all of the first five refused to participate unless they received individual therapy. This became a problem that needed to be dealt with quickly to avoid losing participants. It was also a strong indication of the limited acceptability of group therapy in the context of this study. It was therefore decided to modify the aims and design of the project to a) compare individual versus combination therapy only; and b) to introduce a delayed therapy control group. Participants accepted the combination therapy. The introduction of the control group improved the methodological quality of the study as it increased confidence that any potential gains were due to therapy rather than just recovery with time. The control group was randomised to individual or combination therapy at the end of the waiting time. This ensured that all participants in the project received therapy as originally planned and ethically appropriate. Ethics approval was obtained for this modification.

This study was therefore a randomised, single blinded trial employing a delayed therapy control design. Repeated measures were taken: a) at four time points for those allocated in a therapy group: twice before therapy (double baseline), once after therapy, and once three months later/ follow up; b) at five time points for the delayed therapy

control group – double baseline as for the therapy groups, third baseline (at the same time point as post therapy for the therapy groups), post therapy, and follow up.

The study also included a pilot study with a small number of participants prior to the randomised study. The main aims of the pilot were to assess the acceptability of the study procedures, treatment and outcome measurement. The pilot methods and results are described in chapter 4.

3.2 Ethical approval

Ethical approval was obtained in both Greece and the United Kingdom. In Greece, the project was evaluated by two research ethics committees (RECs): The University Hospital of Patras (42/19.02.2013) (Appendix B), for participants recruited from Achaia, and the University of Athens Eginitio Hospital (325/16-01-13) (Appendix C) for participants recruited from Attica. All recruiting sites in Attica accepted the Eginitio Hospital REC approval. In the UK, the project was approved by the Division of Language and Communication Science's Proportionate Review Committee of the School of Health Sciences, City, University of London (PhD/12-13/17) (Appendix D).

3.3 Recruiting sites

Participants were recruited from one of the following five state hospitals in Attica: Eginitio General University Hospital of Athens, Evangelismos Hospital, General Hospital of Athens G. Gennimatas, Attiko Hospital, National I Rehabilitation Centre, and from private rehabilitation centres (Filoktitis, Anaplasi, Iatriki Askisi), and from the University Hospital of Patras in Achaia.

3.4 Participants

Participants were identified, approached and recruited through state hospitals and private rehabilitation centres in Attica and Achaia participating in the Thales Aphasia Project. Participants were people with aphasia after stroke, meeting the following inclusion criteria: 1. had a stroke, as reported by their referring clinician, 2. were at least 4 four months post stroke and medically stable, 3. were Greek native speakers, 4. were older than 18 years old, 5. had no history of any other neurological or psychiatric problem, 6. had no considerable cognitive decline [scored ≥ 32 out of 38 on Brief Cognitive Screening Test (Economou & Routsis, 2015), a cognitive test specifically developed for people with aphasia], 7. received no other speech language therapy services during this research. Participants were excluded if they did not live at home prior to stroke and/or had a known history of mental health problems and/or cognitive decline prior to stroke.

3.4.1 Participant recruitment

Members of the Thales Aphasia Project approached Neurologists and Speech and Language Therapists working in state hospitals and private rehabilitation centres and provided them with information about the project. This resulted in establishing five state hospitals and three private rehabilitation centres in Attica and one hospital in Patras, as indicated above, as recruiting sites. For each site of recruitment, one main referring clinician became the link person of that site to the Thales project. Link clinicians from the recruiting sites referred potential participants to four Neuropsychologists of the Thales project. The Thales Neuropsychologists visited potential participants, provided information on the project using aphasia friendly information sheets, and answered any questions they may have had. They asked those interested to take part for permission to access their medical records in order to obtain information about stroke and relevant medical history and check eligibility for the study (Appendix E). Those eligible were visited again, screened for cognition and written consent was obtained.

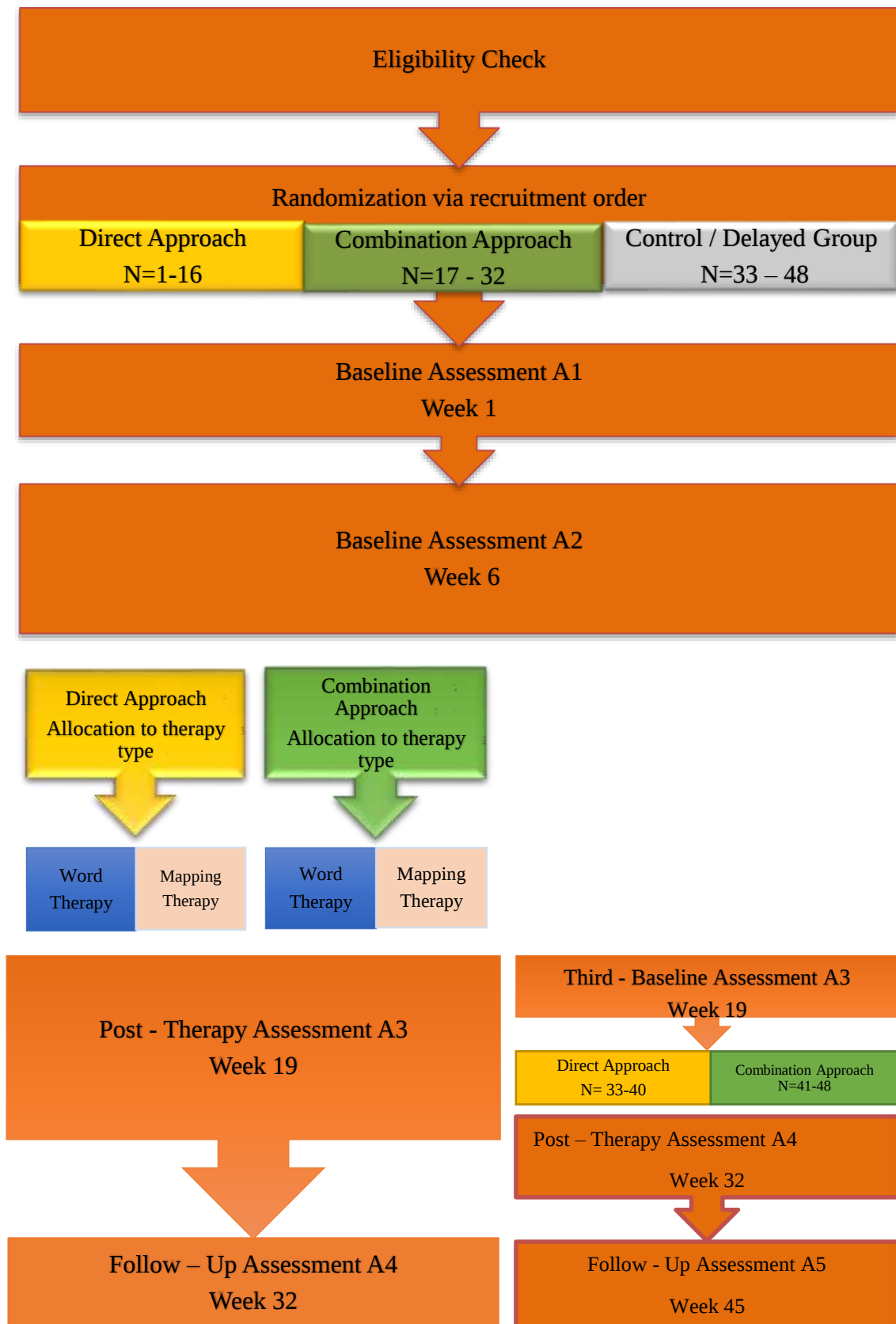
Participants were then screened with the Brief Cognitive Screening Test (Economou & Routsis, 2015), which is a non-verbal test suitable for checking cognition in people with aphasia. It incorporates three tasks of the Mattis Dementia Rating Scale (DRS) (Jurica, Leitten, & Mattis, 2001): the concepts (identity and difference), the visual identification and the visual memory. It also includes 14 items from the Raven Coloured Progressive Matrices (Raven, 1936). Participants had to achieve a score higher than 32 (out of 38) in order to be able to take part in the project (Economou & Routsis, 2015). Once identified as appropriate for inclusion into the study, participants who were willing to take part signed the consent form (Appendix F) of the study.

3.5 Randomisation procedure

Participants who consented to take part in the Thales Aphasia Project were randomised by recruitment order. The plan was for the first 16 participants to be allocated to the direct therapy, the next 16 to group therapy and the next 16 to the combination therapy. The cycle would be then repeated aiming to recruit 96 participants. However, the protocol had to be modified as participants refused to have group therapy only (see section 3.1 above). As a result, the first 16 individuals were allocated to direct therapy as originally planned, but the next 16 were allocated to indirect combination therapy; and the next 16 were allocated to a wait list control / delayed treatment group. Participants of this group were randomly allocated to follow direct or indirect combination therapy after completing the waiting time (Figure 3.1: Flow Chart of participants in the study).

Assessors were blinded to randomisation allocation. The assessors had no contact with the treating therapists (the student researcher is one of the treating SLTs) and were asked to not discuss the therapy type with the participant, family or any other staff involved with the study.

Figure 3.1: Flow chart of the study



3.6 Assessment Procedure

Participants were seen in a setting suitable for their needs, i.e. in hospital, in the rehabilitation centre they attended, or at home. Each participant was assessed by the same assessor. Two baseline assessments were carried out: one at study entry and one six weeks later. Each assessment was completed in two sessions (each ranged from 90 to 120 minutes). Those who were allocated to a treatment condition commenced therapy at that point. They received therapy by one treating SLT for 12 weeks. Those allocated to the control group had 12 weeks of no contact with the research team. The assessor then assessed control group participants again before they commenced their therapy. All participants were assessed immediately after treatment and three months later in order to determine whether they maintained any gains obtained during therapy.

Assessments were carried out in the same order for all participants. The first section of the Greek version of the Boston Diagnostic Aphasia Examination (BDAE, Papathanasiou et al., 2008), i.e. the oral language subtests, was conducted first. The picture description task was recorded on audiotape in order to then calculate the CIU of the connected speech. The second and third sections of BDAE and the Greek Boston Naming Test (BNT, Simos, Kasselimis & Mouzaki, 2011) were administered then, followed by the reading and writing sections of BDAE. In the second session, participants completed the Greek Stroke and Aphasia Quality of Life Scale-39g scale (SAQOL-39g, Efstratiadou et al., 2012; Kartsona & Hilari, 2007), the Greek General Health Questionnaire-12, (GHQ-12, Garyfallos et al., 2001), the Greek EQ-5D, (Kontodimopoulos, 2008) and the Oral Confrontation-Naming Task of the Snodgrass and Vanderwart Pictures. The assessor gathered information about the PWA's functional communication abilities by interviewing their main significant other with the American Speech and Hearing Association Functional Assessment of Communication Skills for Adults (ASHA FACS, Frattali, Holland, Thompson, Wohl, & Ferketic, 1995) measure. If the significant other was not present in either of the two sessions, ASHA-FACS was administrated over a phone interview. During the second baseline assessment, the same assessments were repeated, apart from the full BDAE. The Oral Confrontation – Naming

Task was repeated three times before the beginning of therapy, in order to determine therapy material. The measures are described in full in section 3.7 below.

Assessments were conducted in a quiet room with minimal distractions in the hospital, rehabilitation centre or at home. A quiet room was used as a therapy room in each hospital or rehabilitation centre. Speech samples were recorded using a stereo “Zoom” audio recorder (model number: H1 Hand Recorder), with an inbuilt microphone.

3.7 Measures

This section describes the range of measures that were used in this study as profiling and outcome measures. The profiling measure was chosen to provide a detailed description of participants’ aphasia. The primary outcome measure was the one most expected to change with the intervention provided. The secondary outcome measures were chosen to tap on the activity and participation domains of the WHO ICF and also well-being and quality of life (A-FROM). The choice of measures was restricted by what measures were available in the Greek language.

3.7.1 Profiling measure

The Greek version of the Boston Diagnostic Aphasia Examination (Papathanasiou et al., 2008) measure was used to provide information on participants’ aphasia: type and severity.

The Boston Diagnostic Aphasia Examination (BDAE) is a neuropsychological battery used to evaluate adults suspected of having aphasia. Goodglass and Kaplan designed it in 1972. The BDAE is a comprehensive, multifactorial battery designed to assess a broad range of language impairments that often arise as a consequence of organic brain dysfunction. It goes beyond simple functional definitions of aphasia - into the components of language dysfunctions that have been shown to underlie the various aphasic syndromes (Goodglass & Kaplan, 2001). The BDAE evaluates language skills based on perceptual modalities (auditory, visual, and gestural), processing functions (comprehension, analysis, problem-solving), and response modalities (writing, articulation, and manipulation). It provides a diagnosis of presence and type of aphasic

syndrome that leads to inferences concerning cerebral localisation and underlying linguistic processes that may have been damaged. It is used for comprehensive assessment of the patient's strengths and weaknesses in all language areas. There are two different editions of BDAE-3, the long and the short form. The short form was designed as a brief assessment tool for several language aspects in the 3rd version of the BDAE (Goodglass & Kaplan, 2001), to address the need for screening tools that could be administered in a shorter time. The full BDAE was used in the trial as a profiling measure. The full and the short version of the BDAE were used in the pilot (see chapter 4). The Greek versions of the battery were originally translated and culturally adapted by Tsantali et al. (2001) and standardised by Papathanasiou et al (2008). The full and short editions of the Greek BDAE demonstrated excellent test-retest reliability (ICC=0.96), inter - observer reliability and excellent construct validity.

The BDAE is divided into five sections (Spreeen & Risser, 2003). The first section comprises the conversation and expository speech subtests (simple social responses, free conversation, picture description - 'Cookie Theft'). In the second section, auditory comprehension (basic word discrimination, body parts, commands, complex ideational) is tested. Oral expression (nonverbal agility, verbal agility, serial speech, word repetition, repetition of nonsense words, sentence repetition, diction, melody, rhythm, special category naming, animal naming, and response to questions) is assessed in the third section. The fourth section consists of reading subtests (visual discrimination symbols / words, awareness of oral spelling, word reading, matching words with pictures, oral reading comprehension, reading sentences, paragraphs) and the last section of writing subtests (narrative writing, dictated functions, mechanics-motor, oral spelling, written object naming). The BDAE long form takes approximately 60 to 90 minutes to complete and the short one approximately 30 to 45 minutes. Scores are converted to percentile scores for all subtests, including severity rating, fluency, auditory comprehension, naming, oral reading, repetition, paraphasia, automatic speech, reading comprehension and writing.

3.7.2 Primary outcome measure

Oral Confrontation Naming Task of Snodgrass and Vanderwart Pictures: For the present study, the 260 colourised Snodgrass and Vanderwart noun pictures, depicting mostly objects but also animals, vehicles, body parts, and symbolic representations (Rossion & Pourtois, 2004), were used to choose therapy material and as a primary outcome measure. As therapy material was drawn from this measure, it was chosen as the primary outcome, as the naming measure most tightly related to the intervention offered.

Before starting therapy, each participant completed an oral confrontation-naming task of all 260 pictures three times. The pictures were presented in a random order to each participant for naming across three trials, without any cuing or feedback. It took approximately 60 minutes to administer the full set of pictures, using a computerized task, and participants were given a maximum of 13 seconds to respond for each picture. The pictures that a participant failed to name on at least two trials were selected as potential treatment stimuli. This process of stimulus selection resulted in a set of treatment items specific to each participant. 70% of the incorrect responses were selected as treatment material, while the other 30% was used as untreated generalisation stimuli. Not all selected treatment items were used during the therapy procedure. Each participant was trained in a subset that was dependent on participant's success on the probes that were taken during the therapy. The generalisation items will not be analysed in the present thesis; this data will be analysed in future research. At the end of the treatment period and three months after the completion of the treatment program, the same Oral Confrontation Naming Task was carried out, but only once.

In 1980, Snodgrass and Vanderwart normalised the pictures by asking healthy subjects to name the pictures by rating the familiarity, the visual complexity, the name agreement and the degree to which the picture matched the image. The intercorrelations among the four measures were low. Picture names and norms were presented for each picture. The mean and standard deviation for the familiarity of all pictures was (M) 3.84 and (SD) 0.95, in a scale of 1 to 5. Name agreement was measured with the statistic H (0.43) and percentage agreement (93%). H represents a point-estimator for

the distribution of the proportion of different responses given to a particular picture (Shannon, 1948). H can range from 0 to infinity, where values around 0 indicate perfect name agreement and larger values indicate more variation in the names given for a picture. Concept agreement was 93%.

The 260 colourised Snodgrass and Vanderwart noun pictures were validated for familiarity, visual complexity, naming and image agreement in Greek with a group of healthy adults (Papathanasiou, Efstratiadou, Deligiorgi, Archonti & Economou, in preparation).

3.7.3 Secondary outcomes measures

As indicated above, the choice of secondary outcome measures was restricted by what assessment tools that tapped WHO ICF domains were culturally adapted and psychometric tested in the Greek language. The following measures were chosen and are described in this section:

- I. Greek Boston Naming Test (Simos, Kasselimis & Mouzaki, 2011)
- II. American Speech and Hearing Association Functional Assessment of Communication Skills for Adults (ASHA FACS) (Frattali et al., Holland, Thompson, Wohl, & Ferketic, 1995), completed by the carer
- III. Discourse scores from the Cookie Theft Picture Description on the BDAE (BDAE; Goodglass & Kaplan, 1983)
- IV. Greek version of the General Health Questionnaire-12, (GHQ-12, Garyfallos et al., 2001)
- V. Greek Stroke and Aphasia Quality of Life Scale-39g scale (SAQOL-39g, Kartsona & Hilari, 2007; Efstratiadou et al., 2012)
- VI. Greek version of EQ-5D, (Kontodimopoulos, 2008)

I. Greek Boston Naming Test

The Boston Naming Test is a widely used neuropsychological assessment tool to measure confrontational word retrieval in individuals with aphasia. Kaplan, Goodglass and Weintraud developed it in 1983. It was chosen as an outcome measure in this study, as the intervention aimed to improve naming and the BNT is an independent to the specific therapy offered naming measure.

The Greek version of the Boston Naming Test by Simos, Kasselimis and Mouzaki (2011) was used in this study. The Greek version of the BNT was originally translated and culturally adapted for use in Greece by Tsantali *et al.* (2001) and standardised by Atsidakou *et al.* (2014). It demonstrated excellent parallel-form reliability ($r = .96$), test-retest reliability ($ICC = 0.99$), inter- observer reliability ($ICC = 0.99$) and excellent construct validity (Atsidakou *et al.*, 2014). It consists of 45 items, line drawings graded in difficulty. Items are rank ordered in terms of their difficulty to be named, which is correlated to their frequency. The examiner asks the patient to name each picture, and allows a maximum of 20 seconds for a response. The examiner writes down the patient's responses in detail, using codes. If the patient fails to give the correct response, the examiner, at their discretion, may give the patient a phonemic and/or semantic cue. After the patient completes the test, the examiner scores each item with 1 point for each correct response without cueing. Responses after cueing provision or incorrect responses are scored as 0. The total score ranges from 0 to 45, with higher scores indicating a better naming ability.

II. American Speech and Hearing Association Functional Assessment of Communication Skills for Adults (ASHA FACS)

The ASHA-FACS (Frattali *et al.*, 1995) is a measure of functional communication; it does not aim to measure impairment. Rather, the assessment aims to measure how specific speech, language, hearing and/or cognitive deficits affect performance of daily life activities (Frattali *et al.*, 1995). The ASHA-FACS was used as an outcome measure in this study in order to see if any gains in naming achieved through

the intervention resulted in secondary gains in functional communication. Given the assessment load for participants in this study, the ASHA-FACS has the additional advantage of being rated by a person who knows the person with aphasia well.

The ASHA-FACS addresses functional communication across four domains: Social Communication; Communication of Basic Needs; Reading, Writing, Number Concepts; and Daily Planning. Measurement of the 43 functional communication items is based on a 7-point Likert scale of Communication Independence, where 1 = “does not do”, 3 = “does with moderate to maximal assistance”, 5 = “does with minimal to moderate assistance” and 7 = “does”. Summing the scores of items and then dividing by the number of items provides the mean score for each domain, which can range from 1 to 7. Overall, ASHA-FACS scores also range 1-7 and are calculated by adding up the domain scores and dividing by the number of domains. Lower scores indicate greater impairment (Frattali et al., 1995). The ASHA-FACS also yields four qualitative dimensions: adequacy, appropriateness, promptness and communication sharing. These are not used in this study. The ASHA-FACS has demonstrated high inter - rater reliability (0.72 to 0.84). It takes approximately 20 minutes to complete and in our study, it was completed by the person with aphasia’s significant other, typically a spouse or partner. The ASHA-FACS has been formally validated in Greek from Hairi, Halkia and Papathanasiou in 2006.

III. Discourse scores from the Cookie Theft Picture Description on the BDAE

The researchers presented the “Cookie Theft” picture to the participants and asked them to describe it. No more hints or demonstrations were given during the description, aiming to collect the spontaneous narrative performance of the speakers. Their description was recorded and then transcribed. The transcripts served as the speech samples for further analysis. The analysis took place based on the scoring instructions described by Nicholas and Brookshire (1993), including guidelines for scoring and counting words and correct information units (CIUs) and for calculating CIUs/min and %CIUs. According to this standardised rule-based scoring system, words must be intelligible in context in order to be included in the word count. CIUs are those words that are accurate, relevant, and informative relative to the eliciting stimuli. CIUs/min

provides a measure of how efficiently a speaker produces accurate and relevant information; %CIUs measures how much of a speaker's discourse is accurate, relevant, and informative. CIUs/min calculation system has been used in the present study.

IV. Greek version of the General health questionnaire-12

The General Health Questionnaire (GHQ) is a measure of current mental health and since its development, by Goldberg in the 1970s, it has been extensively used in different settings and different cultures. It is a screening tool for depression and high emotional distress. It was selected in this study in order to see if the intervention led to any secondary improvements on participants' emotional distress. The questionnaire was originally developed as a 60-item instrument, but at present a range of shortened versions of the questionnaire, including the GHQ-30, the GHQ-28, the GHQ-20, and the GHQ-12 are available. The 12-item version was used in this study as it has comparable psychometric properties to the longer versions and it is much quicker to administer. The scale asks whether the participant has experienced any particular symptom or behavior recently. For example, "Have you recently...": 1) "Been able to concentrate on whatever you are doing?" 2) "Been losing self-confidence in yourself?" 3) "Felt constantly under strain?" and 4) "Lost much sleep over worry?".

Each item is rated on a four-point scale ("less than usual", "no more than usual", "rather more than usual", or "much more than usual"). Although these responses can be scored using a Likert scale (0-1-2-3), the most common scoring method is bi-modal (0-0-1-1), leading to a score range of 0-12. For people with stroke, scores ≥ 3 indicate high emotional distress (Hackett, 2005). The Greek version of the GHQ-12 was translated and validated by Garyfallos et al. (1991): all validity indices were satisfactory and internal consistency was high (Cronbach's Alpha = 0.77 - 0.93). GHQ-12 is a consistent instrument over multiple time periods with relatively long periods between applications in general population samples (Pevalin, 2000). This makes it particularly well-suited for long term studies that require an indicator of minor psychiatric morbidity (Pevalin, 2000).

V. Greek Stroke and Aphasia Quality of Life Scale-39g scale

The Stroke and Aphasia Quality of Life Scale (SAQOL-39) (Hilari, Byng, Lamping, & Smith, 2003) is an interview-administered self-report scale. Developed from the Stroke Specific Quality of Life Scale (Williams, Weinberger, Harris, Clark, & Biller, 1999) for use in people with long-term aphasia, the SAQOL-39 is a measure of health-related quality of life that taps on aspects that are important to people with stroke and aphasia and are affected by their condition. It was chosen in this study in order to evaluate whether intervention gains led to any perceived benefits for health-related quality of life. In this study, the SAQOL-39g was used, which comprises the same items as the SAQOL-39 but items are grouped into three domains rather than four domains (listed below). The SAQOL-39g includes items from the SS-QOL that have been modified to ensure that they are appropriate for use with individuals with aphasia. The response options and presentation format is also adapted to be communicatively accessible to people with aphasia and additional items relevant to people with aphasia are included (Hilari & Byng, 2001). The SAQOL-39g consists of 39 items, which cover three domains: physical (self-care, mobility, work, impact of physical condition on social life, upper extremities function), psychosocial (personality, thinking, mood, family and social functioning) and communication (language function, impact of language difficulties on family and social life). The response format is a 5 – point scale, ranging from 1-5. In the first part, items are phrased as for example “How much trouble did you have understanding what other people say?”, and answers vary from “Couldn't do it at all” to “No trouble at all”. In the second part, items are phrased as “Did you feel you were a burden to your family” for instance, while responses vary from “Definitely yes” to “Definitely no”. Overall and domain mean scores are calculated, ranging between 1 and 5. Higher scores indicate better quality of life. The Greek version of SAQOL-39g was translated and cross-culturally adapted by Kartsona and Hilari (2007) and further psychometrically tested by Efstratiadou and colleagues (2012). It demonstrated excellent acceptability (minimal missing data; no floor/ceiling effects), test-retest reliability [ICC = 0.96 (overall scale), 0.83– 0.99 (domains)] and internal consistency [Cronbach’s alpha = 0.96 (overall scale), 0.92–0.96 (domains)]. There was strong evidence for convergent [$r = 0.53$ – 0.80 (overall

scale), 0.54– 0.89 (domains)] and discriminant validity [$r = 0.52$ (overall scale), 0.04– 0.48 (domains)].

VI. Greek version of EQ-5D

EQ-5D is a standardised measure of health status, developed by the EuroQol Group aiming to provide a simple, generic measure of health for clinical and economic appraisal (EuroQol Group, 1990). EQ-5D is designed for self-completion by respondents and is ideally suited for use in postal surveys, in clinics, and in face-to-face interviews. It is applicable to a wide range of health conditions and treatments. It provides a simple descriptive profile and a single index value for health status that can be used for clinical and economic evaluation of health care and in population health surveys (EuroQol Group, 1990). It takes only a few minutes to complete. EQ-5D consists of: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The EQ-5D descriptive system comprises the following five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three levels: no problems, some problems, severe problems. The respondent is asked to indicate their health state by ticking (or placing a cross) in the box against the most appropriate statement in each of the 5 dimensions. For health economics evaluations, this decision results in a one-digit number, which expresses the level selected for that dimension. The digits for 5 dimensions can be combined in a five-digit number describing the respondent's health state. The EQ-5D descriptive system was used in the broader project in order to derive a health economics evaluation of the interventions used. This data is not part of this project. The EQ VAS was used in this study. The EQ VAS records the respondent's self-rated health on a 10cm long vertical, visual analogue scale where the endpoints are labeled as "Best imaginable health state" = 100 and "Worst imaginable health state" = 0. This information can be used as a quantitative measure of health outcome, ranging 0-100, as judged by the respondents. Kontodimopoulos and colleagues translated the Greek version of EQ-5D (2008) with good results.

3.8 Sample Size and Power Calculation

The original sample size of 96 participants, suggested in the Thales protocol, was not based on a power calculation, but on an estimate that with about 30 participants per group (allowing for drop outs) the required statistical analyses could be performed. A power calculation however was subsequently performed using the G*Power software. It was found that for a mixed within – between ANOVA to achieve a medium effect size ($f = 0.25$), at an alpha level of $p = 0.05$, a total sample of 78 participants gave 80% power; and a sample size of 92 gave 85% power.

3.9 Data analysis

Descriptive statistics and visual inspection was used to summarise participant characteristics and scores on measures used. As 10 outcome measures were used in this study, to minimize multiple comparisons and present more concise results, visual inspection of data and differences in mean scores were considered before deciding whether further statistical analysis should be undertaken to compare differences between groups and across time with each secondary outcome. Still, a Bonferroni correction was applied for the 10 planned comparisons ($0.5/10 = 0.005$) to the critical probability value. To explore whether there was a significant difference between SFA therapy versus no therapy (control group), mixed ANOVAs were carried out with two levels in the between factor (therapy vs no therapy) and three levels in the within factor (three assessment time points: baseline 1, baseline 2, and post therapy). To explore the efficacy of individual SFA vs. combination SFA therapy approach, mixed ANOVAs were carried out with two levels in the between factor (type of therapy: individual vs. combination) and four levels in the within factor (four assessment time-points: two baselines, post therapy, and follow-up). The control group had one assessment point more than the therapy group at baseline. Thus, for the analyses of individual versus combination SFA, the assessment points of week 6 and week 19 were taken as the two baselines and not those from week 1 and week 6.

To ensure unbiased comparison among the randomised groups, intention to treat (ITT) analysis was used (Sainani, 2010). ITT avoids overoptimistic estimations of the efficacy of a therapy, which results after removing non-compliers (Gupta, 2011). According to Fisher et al. (1990), ITT analysis includes all randomised patients in the groups to which they were randomly assigned, regardless of: a) their adherence with the entry criteria, b) the treatment they received, and c) subsequent withdrawal from the treatment or deviation from the protocol. The Last Observation Carried Forward (LOCF) method of ITT was used in this study. This technique replaces a participant's missing values after dropout with the last available measurement and assumes that the participant's response would have been stable from the point of the dropout to trial completion, (rather than worsening or improving) (Gadbury, Coffey, & Allison, 2003; Molnar, Hutton, & Fergusson, 2008).

3.10 Therapy

3.10.1 Therapy Type

As described in chapter 1.8.1, in the present study, word level therapy focused on improving the recalling ability of words, by creating and developing a list of semantic traits related to a specific concept (Semantic Feature Analysis). Semantic feature analysis (SFA) is a treatment for lexical retrieval impairment, in which participants are cued to provide semantic information about concepts that are difficult for them to name aiming to facilitate accurate lexical retrieval (Boyle, 2004). ESFA therapy is a modified version of Semantic Feature Analysis (SFA) therapy. It is based on the SFA approach, but also prompts the individual, after word retrieval, to elaborate the features elicited, into a sentence. It also includes provision of elaborate cueing hierarchies to elicit features when participants cannot produce them. Moreover, during ESFA therapy, participants are encouraged to write the features on the chart, as writing can be developed into a self-cueing strategy. Like SFA, ESFA therapy aims to improve word retrieval, by focusing on strengthening the connections between the target word and its semantic network.

Additionally, ESFA aims to enable the individual to transfer their naming abilities to connected speech.

3.10.2 Therapy Approaches tested

Direct (individual) and indirect (combination) ESFA were tested. Direct ESFA comprised three 1-hour sessions of individual therapy per week for 12 weeks (36 hours of therapy in total). Combination ESFA comprised two 45-min sessions of individual therapy and one 90-min group therapy (n=2-4) per week for 12 weeks (36 hours of therapy in total).

3.10.3 Treatment duration, dosage and intensity

There is no straightforward or consistent definition of intensive therapy in the field of aphasia. Intensity of therapy has been defined either in terms of the number of hours per week or, more generally, as therapy provided at a rate greater than usual (Hinckley & Craig, 1998). Classification of therapy as “non-intensive” and “intensive” varies greatly.

The findings of a meta-analysis by Bhogal et al. (2003) reported better recovery from aphasia in participants who had shorter intervention [mean (SD) = 11.2 (1.7) weeks] and more intense [8.8 (2) hours], than those who had longer [22.9 (2.3) weeks] and less intense [2 hrs] intervention. From the 10 studies reviewed in the meta-analysis, five were positive and five were negative studies. When examining the outcomes related to the amount of therapy provided, it appeared that the positive studies provided an average of 7.8 (5 to 10) hours of therapy per week for 11 (8 to 12) weeks, compared to the negative studies that only provided 2.4 (2 to 3.8) hours per week for 22.9 (20 to 26) weeks. Taking the above into account, we decided to have a 12-week therapy period.

Aiming to decide how many hours of therapy should be offered per week, the following findings were considered. Greener (2003) suggested that the current treatment of people with aphasia in hospitals in the UK consists of two therapy sessions per week,

each lasting approximately one hour. Bakheit et al. (2007) called this ‘standard’ therapy. Bakheit et al. found that providing 1.0 to 4.3 hours of therapy per week, as soon as possible after the onset of stroke, did not result in a statistically significant difference in language function, compared to therapy that was provided for 0.5 to 1.6 hours/week for the same duration. Moreover, they documented that only a small number of patients was able to tolerate an average of four hours of speech and language therapy per week in the early period after stroke, and this did not have an advantage over treatment given for approximately two hours per week. In their review of aphasia therapy trials, Brady et al. (2012) compared intensive vs. non-intensive interventions and found that, across the trials, significantly more participants (41) withdrew from the high-intensity SLT intervention groups, in comparison with those withdrawn from low-intensity SLT interventions (23) ($p = 0.03$, OR 2.01, 95% CI 1.07 to 3.79). Taking the above into account, three-hours per week was determined as appropriate dosage for the present project.

3.10.4 Treatment Fidelity

Treatment fidelity is defined as the strategies that monitor and enhance the accuracy and consistency of an intervention to ensure that therapy is implemented as planned and that each of its component is delivered in a comparable manner to all study participants over time (Smith, Daunic, & Taylor, 2007). In this study one specific aspect of fidelity, treatment integrity (TI) was evaluated. TI refers to how well a treatment condition is implemented as planned (Yeaton & Sechrest, 1981; Vermilyea, Barlow, & O’Brien, 1984), in other words how well treating researchers adhere to the treatment protocol in a study.

Three treating therapists provided therapy, all of whom were experienced speech and language therapists with more than three years of clinical experience. To ensure treatment integrity, the following procedure was used. Firstly, a detailed scripted treatment manual was created, by two of the therapists, including both therapy types and approaches, and was provided to all treating therapists. Secondly, all therapists undertook a structured training (Burgio et al., 2001), during which therapists set a scene and played

a scenario, with one therapist taking the role of the PWA and the other the therapist's. The training gave therapists the chance to develop their skills in different situations (e.g. individuals with global aphasia, with anomia, with dysarthria and dyspraxia of speech). Thirdly, another therapist observed each therapist in three sessions and provided feedback on how closely they followed the manual.

As the research student was one of the treating therapists in this study, a separate study led by a Master's student ran in the second year of the project (Kladouchou et al., 2017; see appendix G for full paper). The research student was a collaborator and co-author in this study but was not involved with the analysis of the data and the reporting of the results. The study investigated the TI of the ESFA aphasia therapy as delivered in individual and group therapy sessions and checked the degree to which therapists implemented treatment as intended by the treatment protocol. Two ESFA integrity checklists were developed, one for the individual and one for the group therapy, based on the ESFA manual. Therapy videos (n=15) from the three-treating speech and language therapists (SLTs) were collected for analysis, while treating SLTs' views on what facilitates TI were also explored through a survey. 33% of the video sample (n=5) was analysed for reliability, with Kappa statistics. Results showed an excellent inter-rater reliability ($.75 \leq \kappa \leq 1.00$) for all but one video ($\kappa=.63$). Intra-rater reliability ($.75 \leq \kappa \leq 1.00$) was excellent for all five videos checked. A high TI level (91.4%) was reported. Both approaches had high TI; individual sessions had a significantly higher level of TI (94.6%) compared to group sessions (86.7%), [$t(13) = 2.68, p=.019$]. Findings regarding SLTs views on TI revealed that all SLTs found training, use of treatment manual, supervision, and peer support useful in implementing ESFA therapy accurately. In conclusion, the present study showed that ESFA therapy as was delivered in Thales is well described and therapists can implement it as intended.

3.10.5 Therapy Procedure

The therapy procedure is described here following TIDiER guidelines (Hoffmann et al. 2014). A full description of the intervention following the TIDiER checklist is included in the fidelity paper in Appendix G

3.10.5.1 Main Therapy Principles

As has already been indicated, ESFA therapy is based on SFA therapy but differs in aspects, including provision of elaborate cueing hierarchies to elicit features when participants cannot produce them, and elaborating the features generated into phrases and a sentence. Moreover, during ESFA therapy, participants are encouraged to write features on the chart; however, as writing itself is not a target of the ESFA therapy, the therapist helped with writing if needed and writing errors were not corrected.

In terms of ESFA therapy procedure, the clinician initially asked the participant to draw a picture from the treatment material set and to name it. Then, presenting a semantic features chart (same as that shown in Boyle (2004), but translated in Greek language), the therapist prompted the participant to think of and say words semantically related to the target word (semantic features). The chart included six categories: *superordinate category*, *use*, *action*, *physical properties*, *location*, and *association*. To elicit feature production, the therapist asked questions or provided the participant with sentence-completion cues. For instance, for the *superordinate category*, a question such as “*What category does it belong to?*” was provided. Similarly, for the category *use*, a statement such as “*You use it to/for _____*” was given. After the oral production of the word, which is the focus of ESFA therapy, the clinician prompted the participant to write down the elicited features in the chart. For participants with writing difficulties, the therapist helped them with an alphabet board (e.g. by pointing to the letters they needed). For participants who could not write, the therapist filled in the chart.

After the chart completion and the retrieval of the word by the participant, the therapist encouraged the participant to produce phrases with the target word and each of its features. If needed, the clinician and participant would say the words together or the clinician would point to the target and a feature for the participant to put them together in a phrase. Then, the participant was encouraged to produce a sentence, including the target word and at least one of the elicited semantic features. For example, for the item ‘table’, the individual was asked to produce features such as: *piece of furniture*, *for dining*, *made of wood*, *kitchen*, *chair*, *tea*, *eat*, and then to elaborate these features in sentences such as: *we eat at the table*, *we have tea at the table*, *the table is for dining*, *the table is a piece of*

furniture in the kitchen, etc. Elaboration of features was achieved by asking the individual to choose as many features as they wanted (one as a minimum) and to put them together into a sentence. Participants had first to produce the sentence orally and then if they could, to write the sentence down. The above procedure and strategy was followed for all treatment items. It did not matter if people made errors in their sentences, e.g. syntactic or morphological errors, as long as the sentence was meaningful. After its completion, the chart was used as help/cueing as and when needed.

At the end of each session the participant had to name all trained items of his /her subset of words. These items had been worked on during the previous therapeutic sessions. If a target word was retrieved correctly for three consecutive sessions, without prompt or help by the therapist, and the participant was able to produce correct sentences without cues or reference to the chart, this word was removed from the therapy process (chart completion) and another new word was selected from the treatment material. The participant selected the new word by drawing a picture from the treatment material set. Subsequently, at the beginning of each therapy session, the participant was asked to name the target words that they had not named correctly in the previous session and to produce one sentence for each. If the participant did not name the picture correctly, the chart analysis was repeated with these targets before moving on to new targets.

3.10.5.2 Additional Therapy Principles

In terms of the order of chart completion, there was flexibility. At the first therapy sessions, the therapists would start for animate nouns, e.g. ‘dog’ with the first category (*superordinate* category), e.g. ‘what is it?’ or ‘what group does it belong to?’ and for inanimate nouns, e.g. ‘scissors’ with the *action* category, e.g. ‘what do you do with it?’ or the *use* category, e.g. ‘we use it for...?’, and then work their way through the other features in the following order: *physical properties*, *location*, and *association*. However, as the participants became familiar with the technique, they could spontaneously generate features out of sequence. When this happened, the features were written in the appropriate boxes on the chart, and if and when needed the clinician resumed eliciting features in the

prescribed order, skipping over the categories that the participant had spontaneously completed. If a category was not applicable for a target word, such as when *use* and *action* categories are similar (e.g. for paintbrush: to paint), then this category was skipped by the therapist and only those deemed appropriate for the target item were elicited. If a participant named the target picture on confrontation or during the features generation, the therapist still asked for all features to be produced, in order for the participant to build up semantic links, promoting spreading activation to related semantic concepts. This also aimed to develop feature generation as a compensatory strategy by encouraging the establishment of the technique and its use and, through repeated practice, to increase the chances of a more automatic use of the technique when lexical retrieval difficulties were encountered. The participant was prompted to produce as many features as possible for each category, which were then written in the category box, as more related words facilitate the connections of the semantic network. Some categories elicited more features compared to others: the *physical properties category*, for example, typically had several entries, whereas the box for *superordinate category* had fewer. The production of more than one feature for each category was not an integral component of ESFA though; one semantic feature for each category was the basic requirement. The number of the pictures worked on in each session depended on the participant's performance.

During the therapy, the therapist provided cues to participants, following a specific cueing hierarchy based on the participant's response and type of paraphasia produced. The hierarchy followed is presented in the integrity checklists (Supplemental Materials in appendix H). If the participant was not able to produce the word after cueing, they were led through the entire SFA chart, with cues provided as needed, to produce the target word. When the participant could not produce the target word even when all features had been listed, the clinician produced the word orally and then the participant repeated it and named all of its features.

3.10.5.3 Tailoring

Therapists followed ESFA therapy as described in the treatment protocol. However, therapists' responses took into consideration the participant's aphasia type and performance. Cueing during feature generation followed a specific hierarchy depending on the type of paraphasia produced. As indicated above, while completing the chart, the therapist prompted the participant to write down the elicited features. For participants with writing difficulties though, the therapist helped them to write the features with an alphabet board (e.g. pointing to the letters they needed). For participants who could not write, the therapist filled in the chart. In phrase production, the therapist encouraged the participant to produce phrases with the target word and each of its features. If needed however, the therapist and participant would say the words together or the therapist would point to the target and a feature for the participant to put together in a phrase. Similarly, during sentence production, help was given to participants according to their abilities: people with global aphasia for instance, needed more cues from the therapist compared to people with fluent aphasia, while over time, therapist's help was reduced.

3.10.5.4 Group therapy

During the group therapy sessions, the same principles and criteria as in the individual therapy were followed. The process was more complex as the therapist had to consider more issues in the stimulus selection and the treatment procedure. For stimulus selection the same procedure was followed as in the individual therapy. The only difference was that for the final stimulus selection for the group the results of all administrations of all individuals (2 to 4) in the group were compared. Those pictures that all group participants failed to name on at least two of the three trials were selected as treatment words. Although, the treatment items were the same for all group members, the stimulus selection resulted in a personal set of treatment and probe items in terms of content and number of items.

Participants in each group had different aphasia types and severities. The same procedure was followed as the individual therapy sessions but the participants were asked in turns to take part in the treatment procedure. The therapist controlled turn taking to

ensure individuals got similar amounts of exposure to targets and cues. Specifically, the therapist would put the set of cards in the middle and ask the group member on her right hand side to pull a picture from the treatment material set and to name it. Then a semantic feature chart was presented in front of all the members of the group and the therapist prompted each individual in turn, going clockwise, to generate a feature until all six features were generated and written on the chart. The prompting to elicit features comprised questions or sentence-completion cues. After the chart completion, each participant in turn named the target word. The same procedure was used for the next steps: a) phrase production with the target word for each of its features, and b) sentence production, including the target word and at least one of the elicited semantic features.

In addition, while during the initial therapy session the therapist provided phonological or semantic cues as needed, over time, this changed. After two to three group sessions, group members with mild to moderate aphasia severity started to provide cues to members with more severe aphasia that were struggling to produce the feature or the target word, or provided help during writing the features in the chart by pointing to the letters needed at the alphabet board. In this way, the therapist gave the opportunity to group members to interact with each other. The therapist followed the principle of the protocol whilst being mindful of not disturbing peer-to-peer interactions.

3.10.5.5 Intervention Providers

ESFA therapy providers in this study were three research speech and language therapists (SLTs) who were trained in ESFA and delivered the treatment in the Thales aphasia project. All three participants had a Master's degree, four to nine years of clinical experience and had worked with PWA from two to seven years.

3.11 Summary

This chapter described the design of the study, including changes from the original design, the randomisation process, and the participant inclusion and exclusion criteria, recruitment and flow in the study. The procedures of the study were then detailed and the measures used (profiling, primary and secondary) were described. The methods of data analysis were highlighted. Lastly, ESFA, the therapy tested in this study was described in detail and its fidelity checking was reported.

The next chapter will present the pilot of the study. Chapter 5 will detail the results of the project.

Chapter 4: Pilot study

4.1 Pilot Study Aims

Study procedures were piloted with four participants. The aims of the pilot study were: 1. to assess the feasibility of the study procedures, in particular time needed to complete tests; whether the planned order of administration worked well; and whether there were any missing data and drop outs; and 2. to collate preliminary data on the efficacy of the intervention, by looking at whether there were any trends in the outcome measure scores across time; particularly for the primary outcome. Given the small number of participants, responses to the intervention on the primary outcome were also explored in more detail, by also looking at generalisation to untreated items.

Methods and results for the pilot testing are presented in this chapter.

4.2 Methods

4.2.1 Participants

Four participants constituted the sample of the pilot study. They were the first four participants recruited in the pilot. Three of them were recruited from Eginitio Hospital and the fourth from a private clinic in Athens. The participants met the inclusion criteria for the study, as set out in the previous chapter. They were native Greek speakers with aphasia due to a left-hemisphere ischaemic stroke and had no other history of neurologic impairment. Each had been discharged from speech-language treatment, and none received any additional therapy while participating in this study. Information about the participants' stroke and relevant medical history was extracted from their medical notes to check their eligibility and, at their first appointment, participants completed the Brief Cognitive Screening Test (see table 4.1). They all scored >32 out of 38, and were therefore eligible to take part in the pilot study.

Table 4.1: Outcomes of Brief Cognitive Screening Test

	GP	CS	BA	TT
Mattis DRS: Concept Task	16/16	14/16	16/16	13/16
Mattis DRS: Visual Identification Task	4/4	4/4	4/4	4/4
Mattis DRS: Visual Memory Task	4/4	4/4	4/4	4/4
Raven	14/44	14/14	14/14	12/14
Total Scores	38/38	36/38	38/38	33/38

4.2.2 Experimental Design Process

A single-blinded design was employed to collate preliminary evidence on treatment efficacy, acquisition of treated items, and generalisation to untreated items. Repeated measures were collected, at four time points: twice before therapy (double baseline), once after therapy and once three months later. All participants followed the same treatment approach: direct (individual) Elaborated Semantic Feature Analysis (ESFA).

4.2.3 Procedure

Two baseline assessments were carried out: one on study entry and one six weeks later. As described in Methods, pages 84-88 each baseline comprised more than one session. The first baseline assessment comprised two sessions. In the first session participants completed the BDAE (including the BNT), and in the second session the SAQOL-39g, GHQ-12, EQ-5D and Snodgrass and Vanderwart Pictures (oral confrontation naming). For the oral confrontation-naming task, participants were asked to name the pictures, which were presented in random order, and were scored as either correct or incorrect. Correct responses were intelligible productions of the target word

produced within 13 seconds from their presentation. Self-corrections were allowed. The assessor also completed the ASHA-FACS with participants' significant others (for TT, CS and GP their wives and for BA his mother).

The second baseline assessment was completed six weeks after the first one. All assessment tools were evaluated again as in the first baseline, with the exception of the BDAE, for which instead of the long form the short one was used. The short form is measuring the same categories as the long form of BDAE, but it is briefer. Short BDAE scores can be derived from the long form. Thus, scores from the long form were derived for baseline one and compared with baseline two to check whether the participants' aphasia remained stable. At baseline 2, all measures were completed in one session, except for the Snodgrass and Vanderwart Pictures testing. Participants were then visited three more times to complete the Snodgrass and Vanderwart Pictures testing, in order to identify items for training in the therapy. The three sessions were carried out within one week during this phase.

Treatment was delivered as described in the methods section 3.10.5 pages 102 - 107. Therapy material was chosen based on the results of the three oral confrontation naming trials; pictures that a participant failed to name on at least two trials were selected as potential treatment and untreated stimuli. This process of stimulus selection resulted in sets of treatment items that were unique for each participant. 70% of the incorrect responses were selected as treatment material, while the other 30% was used as untreated generalisation stimuli. Confrontation naming for treated pictures took place at the end of each treatment session, as well as post therapy and three months after the end of the therapy. Confrontation naming for control and generalisation to untreated pictures took place at the end of the therapy process and at follow-up.

Post treatment testing was conducted within a week from treatment completion. The same procedure as in the first baseline assessment was followed. The follow-up session was completed three months after the treatment program ended. Participants did not receive any speech and language therapy services during these months. The same format as in the first baseline session was followed in the follow-up session.

One aspect that is different from the main methods and needs to be highlighted is the use of the BDAE. Before the pilot the BDAE was considered as both a profiling and an outcome measure. Therefore, it is presented here in the pilot as an outcome measure and reasons for not including it as an outcome measure in the main trial are highlighted.

To ensure blinding of assessors, a different assessor from those who assessed participants at baseline, evaluated individuals post therapy, so that they would not know if people were at pre or post therapy stage. The assessors had no contact with the treating therapists (the writer is one of the treating SLTs) and were instructed not to discuss the therapy or what stage of the study the participant was at with the participant, family or any other staff involved in the study.

4.3 Results

4.3.1 Participant characteristics

The four participants were all men. Table 4.2 details their characteristics. GP was 62 years old, married, seven months post stroke, fluent, with Anomic aphasia and dysarthria of speech. His spontaneous speech presented with frequent pauses that included fillers (e.g., “uh” and “um”), with semantic and phonemic paraphasias, and with repetitions and reformulations. He rarely used any overt strategies, such as circumlocution or gesturing, to retrieve words. CS was 48 years old, married, seven months post stroke, non-fluent, with Global aphasia. BA was 43 years old, single, 50 months post stroke, non-fluent, with Broca’s aphasia and severe apraxia of speech. TT was 84 years old, married, six months post stroke, non-fluent with Global aphasia.

Table 4.2: Participants' Characteristics in Pilot Study (n=4)

Participant	Age	Gender	Time post stroke (Months)	Education Years	Aphasia Type	Aphasia Severity
GP	62	Male	7	16	Fluent	Mild
CS	48	Male	7	12	Non-fluent	Severe
BA	43	Male	50	14	Non-fluent	Moderate
TT	84	Male	6	8	Non-fluent	Severe

4.3.2 Feasibility of assessment processes (pilot aim 1)

The average times of each assessment at each baseline are outlined in Tables 4.3 and 4.4 below. In general, people with severe aphasia, such as TT and CS, took less time compared to people with mild aphasia, such as GP, or people with aphasia and apraxia of speech. In particular, when an individual had severe aphasia and was not fluent or verbal, as TT and CS for example, some sections of BDAE were not fully evaluated. This was because the BDAE has discontinuation rules: if an individual does not respond or say anything for the first three items of an oral expression subtest, then the assessor stops this subtest and moves to the next. If an individual respond but with incorrect productions, the subtest is fully assessed. BNT administration was discontinued when six consecutive incorrect responses occurred. Individuals with aphasia and apraxia or dysarthria of speech needed more time to complete the assessment process, as self-corrections or trying to correct articulation prolonged the evaluation time.

All individuals completed the first baseline assessment process in two sessions. None of them needed an extra third session. BA needed the longer time for completing the process (105 minutes for session one), because of his apraxia of speech. BA was the only individual who required a break; a ten-minute break was given in the first session, just after the evaluation of BNT.

Table 4.3: Average time for each assessment tool during Inclusion and Baseline Phase

	Inclusion Phase	Baseline 1 Phase	
	Session 1	Session 1	Session 2
Information questions, consent, demographic questionnaire	30 minutes		
Brief Cognitive Screening Test	15 minutes		
BDAE Full		45 - 90 minutes	
BNT		15 minutes	
SAQOL-39g			15 -25 minutes
GHQ -12			5 - 7 minutes
EQ-5D			3-5 minutes
Oral Confrontation-Naming Task			60 minutes
Total Time:	45minutes	60 – 105 minutes	~85 - 100 minutes

In Baseline 2, the assessment process was completed in four sessions, each of which ranged from 60 to 95 minutes (see Table 4.4).

Table 4.4: Average time for each assessment tool during Second Baseline Phase

	Second Baseline Phase			
	Session 1	Session 2	Session 3	Session 4
BDAE Short	30 - 45 minutes			
BNT	15 minutes			
SAQOL-39g	15 -20 minutes			
GHQ -12	5 - 7 minutes			
EQ-5D	3 - 5 minutes			
Oral				
Confrontation-Naming Task		60 minutes	60 minutes	60 minutes
Total Time:	~ 70-95 minutes	60 minutes	60 minutes	60 minutes

Post-therapy and follow-up sessions were the same as the first baseline and lasted about the same time. None of the individuals needed an extra session for completing the assessments. Only CS took a ten-minute break after completing the BDAE.

As indicated above, scores for the short BDAE can be derived from the full BDAE. Full BDAE scores of baseline 1 were converted to short BDAE scores and compared to baseline 2 to see if participants' aphasia remained stable. Table 4.5 details this comparison. On auditory comprehension, scores for all participants were within 3/64 points, with the exception of GP, whose scores increased by 6.5 points from the first to the second assessment. On oral expression, participants' difference scores varied 1-15 points out of 125, with BA having the highest increase in his score. For reading, scores were stable for three participants (difference scores 0-2 out of 32) and BA's score increased by 6 points. For writing, scores were stable with a difference score of 0 for three participants and a decrease of 3 out of 45 points for GP. We do not know what normal

variability is in these scores. Allowing for a 10% normal variability, GP and BA scores exceeded this criterion for one out of four BDAE domains (oral expression for GP and reading for BA). In summary, BDAE scores remained relatively stable across baselines.

Table 4.5: Comparing BDAE Full to BDAE Short from 1st Baseline and 2nd Baseline Assessment

BDAE	GP	GP	CS	CS	BA	BA	TT	TT
Trial	1 st BA	2 nd BA	1 st BA	2 nd BA	1 st BA	2 nd BA	1 st BA	2 nd BA
Auditory Comprehension								
Word Distinction	29,5/32	32/32	10,5/32	17/32	30/32	31/32	12,5/32	10/32
Body Part Distinction	10/10	9/10	0/10	0/10	9/10	10/10	5,5/10	3,5/10
Commands	13/14	13/14	3/14	0/14	13/15	9/14	1/14	0/14
Complex Ideational	3/8	8/8	1/8	0/8	7/8	7/8	0/8	3/8
Total Aud. Compr.	55,5/64	62/64	14,5/64	17/64	59/64	57/64	19/64	16,5/64
Oral Expression								
Verbal Agility	8/14	12/14	0/14	0/14	3/14	5/14	5/14	2/14
Serial Speech	5/6	3/6	0/6	0/6	4/6	5/6	5/6	1/6
Diction, Melody, Rhythm	2/3	2/3	0/3	1/3	2/3	3/3	2/3	2/3
Word Repetition	4/4	3/4	0/4	0/4	1/4	1/4	4/4	4/4
Low Frequency Phrase Repetition	3/8	2/8	0/8	0/8	0/8	0/8	0/8	0/8
Answer Questions	21/30	20/30	0/30	0/30	14/30	22/30	3/30	0/30
Picture Naming	48/60	47/60	0/60	0/60	37/60	40/60	0/60	0/60

Total Oral Expression	91/125	89/125	0/125	1/125	61/125	76/125	19/125	9/125
Reading								
Word Reading	13/18	18/18	0/18	0/18	6/18	12/18	0/18	0/18
Sentence Reading	4/5	1/5	0/5	0/5	0/5	0/5	0/5	0/5
Words – Pictures Matching	6/6	6/6	0/6	0/6	6/6	6/6	0/6	0/6
Sentence – Paragraphs Understanding	3/3	3/3	0/3	0/3	2/3	2/3	0/3	0/3
Total Reading	26/32	28/32	0/32	0/32	14/32	20/32	0/32	0/32
BDAE	GP	GP	CS	CS	BA	BA	TT	TT
Trial	1st BA	2nd BA	1st BA	2nd BA	1st BA	2nd BA	1st BA	2nd BA
Writing								
Writing Capacity	4/5	4/5	2/5	2/5	3/5	3/5	1/5	0/5
Word Dictation	7/10	7/10	1/10	2/10	6/10	7/10	0/10	0/10
Writing Naming Objects	5/6	6/6	0/6	2/6	5/6	3/6	0/6	0/6
Narrative Writing	1/5	1/5	0/5	0/5	1/5	1/5	0/5	0/5
Total Writing	17/26	18/26	3/26	6/26	15/26	14/26	1/26	0/26
BNT	25/45	22/45	0/45	0/45	11/45	11/45	0/45	0/45

BA: Baseline Assessment

4.3.3 Synthesis of results for pilot aim 1

The first aim of the pilot study was to assess the feasibility of the study procedures, by examining a) the duration of the whole assessment process, b) whether the administration plan worked well and c) whether any missing data and drop outs occurred. The planned order of assessments worked well. There were no missing data or dropouts. The duration of the first baseline assessment varied from 145 to 205 minutes and was completed in two sessions. The second baseline assessment was the longest, comprising four sessions of a total duration ranging from 250 to 275 minutes. Post- treatment and follow-up assessments were completed in two sessions within 130 to 155 minutes. All participants completed all assessments in full in all assessment phases. Researchers discussed with each participant, at the end of each assessment, how they found the number of assessment tools and the time they required to complete. All participants mentioned that the BDAE measure was the longest, but no one complained about the total time taken.

4.3.4 Results on outcome measures (pilot aim 2)

Secondary outcome measures will be presented first and then the results for the primary outcome measure will be detailed. As the primary outcome was completed three times on the second baseline, table 4.6 presents these scores.

Table 4.6: Second baseline Scores of Oral Confrontation-Naming Task of Snodgrass and Vanderwart Pictures (out of 260)

	GP	CS	BA	TT
1st Trial	98	0	126	2
2nd Trial	107	0	124	2
3rd Trial	123	0	127	2

GP's errors during confrontation naming tasks included semantic paraphasias (43%), phonemic paraphasias (50%), no response (5%) and circumlocutions (2%). BA's errors consisted of phonemic paraphasias (78%), no response (10%), semantic paraphasias (7%) and neologisms (5%). CS's and TT's naming ability was severely impaired and their responses comprised non-words (e.g., "uh", "a" and "um") and neologisms.

4.3.4.1 Secondary outcome measures

Scores on all outcome measures at the different assessment points are presented in table 4.7. The secondary outcome measures comprised BDAE, BNT, GHQ-12, EQ-5D, SAQOL-39g, and ASHA-FACS. There was variability in the data. There seemed to be positive changes in all domains of BDAE (four) for all participants: of the 32 comparisons in total between baseline and post therapy and baseline and follow up, 28 were positive. Yet of those, only 11 exceeded a 10% increase in scores. Positive change was shown in the BNT only for participant GP (B1: 25, PT: 31, FU: 33). Emotional distress, as measured by the GHQ-12, seemed to improve for all participants, although they all remained within the high emotional distress range (GHQ-12 total score ≥ 3). The communication domain of SAQOL showed a small improvement for all participants and the improvement was maintained for all except for TT (GP= B1&B2: 2.7, PT: 2.9, FU: 3; BA= B1: 2.6, B2: 3, PT: 3.6, FU: 3.3; CS=B1: 4, B2=3.3, PT: 4.3, FU: 4.4; TT= B1 & B2: 1.1, PT: 2, FU: 1.1). The EQ-VAS scores improved for two participants (GP and BA). A positive trend was shown for ASHA- FACS for all participants, apart from BA.

In summary, it is hard to interpret this data, which is derived from scale variables typically used with groups of people. Moreover, some scales' scores were on a narrow range (e.g. SAQOL-39g). Therefore, it is hard for trends to emerge over and above normal variability by looking at such a small number of participants.

In relation to the main outcome measure, Oral Confrontation Task, the descriptive data suggested that oral confrontation was improved for three of the four participants. Oral confrontation results will be analysed in more detail in the next section

Table 4.7: Assessment outcomes at all assessment phases and all participants of the study

Trial	GP				CS				BA				TT			
	B1	B2	PT	FU	B1	B2	PT	FU	B1	B2	PT	FU	B1	B2	PT	FU
Number of items	BDAE															
(n) or score																
Total Aud. Compr. n=119	101,5		108	113	17		55,5	64	109		110,5	112	16,6		46,5	40,5
Total Oral Expression n=251	145		200	208	4		8	11	94		85	130	32		39	36
Total Reading n=86	66		79	77	12		25	18	46		50	57	3		8	4
Total Writing n=102	76		85	80	13		13	14	56		58	63	1		1	0
n=45	BNT															
	25	22	31	33	0	0	1	1	11	11	11	18	0	0	1	0
	GHQ-12															
n=12	10	9	8	7	8	6	6	5	7	7	4	6	7	7	7	6
N=15	EQ-5D															
	7	7	8	7	8	9	6	6	7	7	7	6	13	12	11	10
	EQ VAS															
0-100	40	50	60	80	70	70	70	70	75	79	89	90	49	52	73	40

Trial	GP				CS				BA				TT			
	B1	B2	PT	FU	B1	B2	PT	FU	B1	B2	PT	FU	B1	B2	PT	FU
0-5	SAQOL-39g															
Physical	4,4	4,1	4,6	4,1	4,7	4,5	4,5	4,9	4,4	4,4	4,4	4,3	1,8	1,5	1,3	1,2
Psychosocial	3,4	3	2,4	2,3	1,3	1	4,75	4,8	4,3	3,7	3,1	3,9	1,3	1,4	1,3	1,6
Communication	2,7	2,7	2,9	3	4	3,3	4,3	4,4	2,6	3	3,6	3,3	1,1	1,1	2	1,1
Total SAQOL-39g	3,7	3,4	3,4	3,1	3,2	2,9	4,6	4,8	4	3,9	3,7	3,9	1,5	1,4	1,4	1,4
1-7	ASHA FACS															
Social	5	5,2	5	6,2	3,7	4	5,1	5,2	6	6	6	4,4	2,9	3	5,9	5,9
Communication	6,6	6,9	6,9	7	5,7	5,9	6,14	7	6,7	6,3	5,33	6,7	3,57	4,2	6	6,6
Communication of Basic Needs																
Reading,																
Writing, Number	4,8	3,2	4,6	6,4	3,8	3,7	4,4	4	6,9	6,9	6,9	6,7	0,4	0,6	2,1	2
Concepts																
Daily Planning	6,4	4,6	4,6	6	1,6	1,8	5,8	6,4	7	6,7	6,4	6,6	0,8	1,1	2	2
	Oral Confrontation Naming Task															
	98								126							
N=260	100	107	238	217	0	0	10	6	125	124	140	135	2	2	6	4
	123								127							
Treated Items	63/65				52/6				44/4				35/47			
					5				7							
					10/18				6/18							
													11/13			
													2/13			

B1: First Baseline Assessment, B2: Second Baseline Assessment, PT: Post – therapy Assessment, FU: Follow-Up Assessment

4.3.4.2 Primary outcome measure

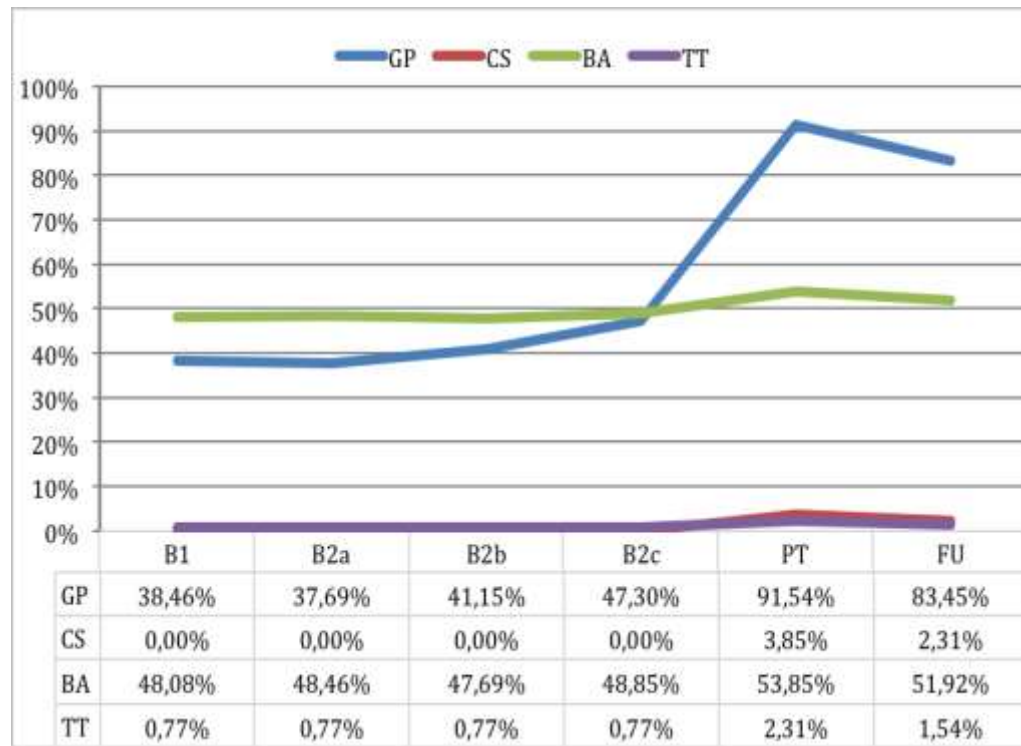
Preliminary data on efficacy of treatment was based on the results of Oral Confrontation Naming Task, which was the primary outcome measure of the study. Data from the four trials in baseline sessions (baselines one and two) were compared to data obtained post-therapy and at the follow-up. For GP, baseline scores ranged 28 – 123 and there was a marked improvement post-therapy: 238, which was largely maintained at follow up: 217. The trend was the same for all participants: CS: 0-0, 10, 6; BA: 124-127, 140, 135; TT: 2-2, 6, 4.

Below, data is presented separately for treated and untreated control items.

4.3.4.2.1 Confrontation Naming of Treated Nouns

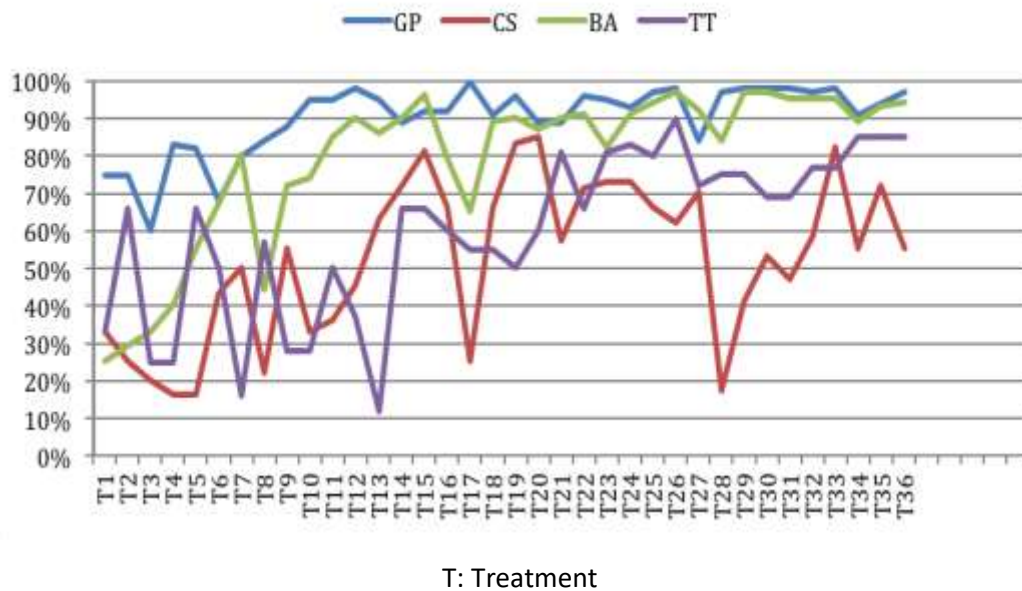
During baseline sessions, GP, BA, CS and TT were able to accurately name $\leq 47,3\%$, 0% , $48,85\%$, and $0,77\%$ of the treatment pictures respectively (see Figure 4.1). Post – therapy sessions showed an improvement in naming ability for all participants: GP $91,54\%$, CS $3,85\%$, BA $53,85\%$, and TT $2,31\%$. In follow-up sessions, three months after therapy, the effects of treatment seemed to be well-maintained for one participant (GP) and somewhat maintained for another two (CS and BA) participants: GP $83,45\%$, BA $51,92\%$, and CS $2,31\%$; this was not the case for TT ($1,54\%$).

**Figure 4.1: Participants' outcomes on Oral Confrontation-Naming Task:
Baseline trials (B1, B2a, B2b, B2c) – Post Therapy (PT) – Follow-Up (FU)**



Detailed data for each participant on confrontation naming of nouns treated during treatment sessions are displayed in the graph below (Figure 4.2). This data is based on *treated* words only. The total number of these words was different for each individual; therefore, the data is presented as percentages.

Figure 4.2: Participants' results for oral confrontation naming of treated words throughout therapy period



Participant GP demonstrated improved naming of treated nouns when ESFA was initiated. His ability to name these nouns continued to improve during therapy. Although he was able to name 52 of 52 (100%) treatment items in session 17 (see Figure 4.2), from session 10 until the end of treatment his more typical performance was between 85% to 96%. Participants CS and TT showed a minimum improvement in post-therapy and follow-up sessions, but their production fluctuated during treatment. With the exception of sessions 15, 19 and 20, where CS indicated a high naming accuracy for 80% to 85% of the target words, his naming accuracy during treatment ranged between 50% and 75%. The number of trained items depended on success in naming during treatment. Participants were trained in different number of items. GP was trained in 65 items, BA in 47, CS in 18 and TT in 13 items. BA showed a small improvement in his ability to name the treatment nouns, but his naming accuracy and his production fluctuated: because of his apraxia of speech, he produced phonemic paraphasias. The number and type of paraphasic errors during confrontation naming tasks revealed a substantial change from pre to post treatment phase for GP, but not for the other participants. GP errors reduced after therapy.

4.3.4.2.2 Generalisation to Untreated and Control Nouns

Generalisation effects were determined based on the criterion used in Boyle's (2004) study. In her study, Boyle defined generalisation in naming as the ability to name at least three more items than the maximum number named during baseline sessions. Only GP demonstrated generalisation to the untreated probe nouns (30% of not named items) after treatment, with maintenance at three months later (Figure 4.3 and 4.4). TT and CS were not able to name any of the untreated items at any assessment phase after treatment. BA named one untreated item post-therapy, but this was not maintained at the follow-up.

Figure 4.3: Accuracy of Responses for Treated and Non – Treated items Post-Therapy

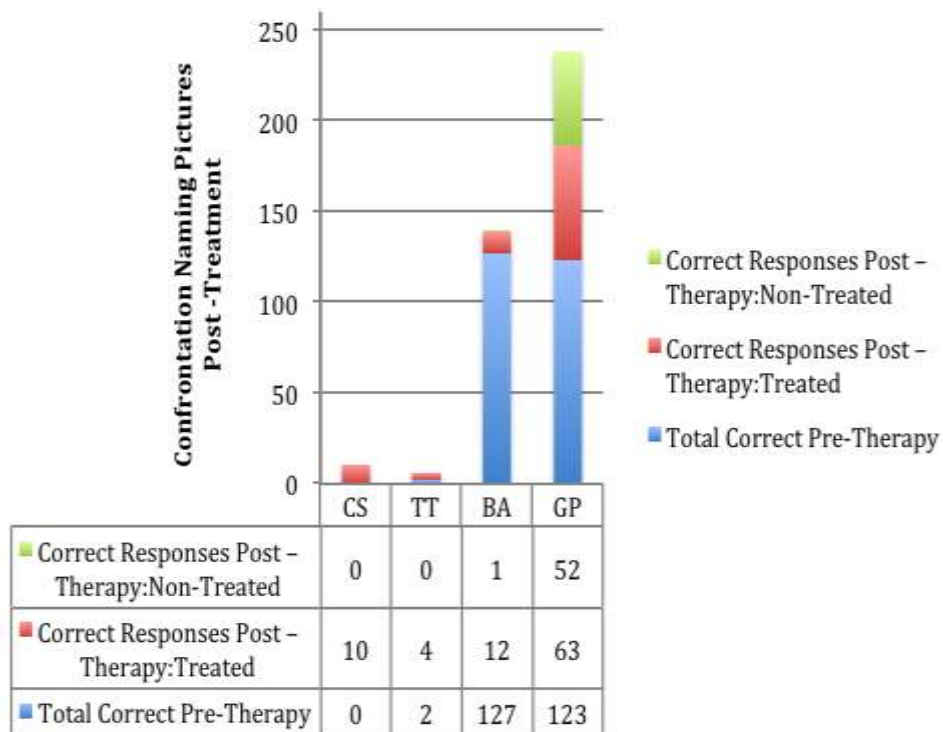
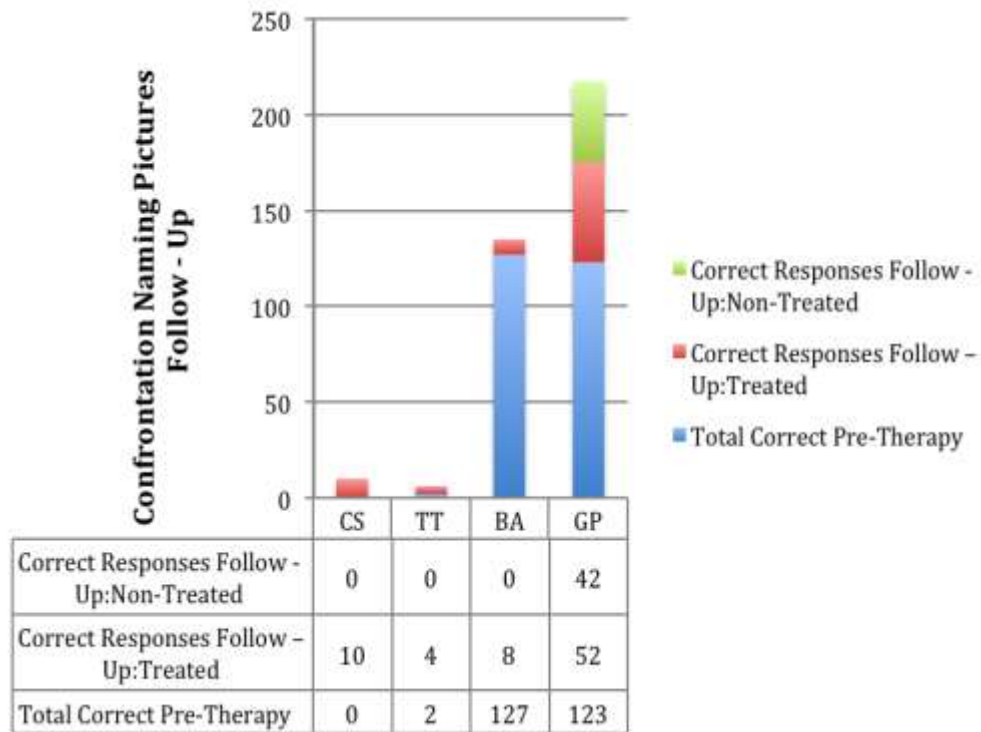


Figure 4.4: Accuracy of Responses for Treated and Non - Treated items at Follow – Up



4.3.4.2.3 Summary of Oral Confrontation Naming Results and Discussion

The preliminary findings of the pilot suggested that ESFA treatment improved the ability to name treated items in three out of four participants, which was maintained for three months following treatment. Generalisation to untreated items occurred only for one participant - GP. GP had mild anomic aphasia and responded as expected, supporting previous literature findings (Boyle, 2004). All other participants had non-fluent aphasia; participants CS and TT presented with Global aphasia in particular. Participant BA presented with Broca's aphasia and apraxia of speech. Analysis of his error responses revealed a high percentage of phonemic paraphasias suggesting a lack of or an inability to access phonologic information of the target word. As Wambaugh and colleagues (2013) stated, different profiles of language deficits may be associated with different responses to semantic feature analysis.

4.4 Summary and modifications resulting from pilot study testing

Results of pilot study showed that a) the planned order for assessments worked well, b) time needed for the completion of assessments was reasonable, and c) no missing data and dropouts occurred. The preliminary findings of the primary outcome measure at the pilot testing also provided positive evidence for the efficacy of the ESFA intervention.

Analysis of the primary outcome results provided interesting insights into participant responses. Given the small number of participants in the pilot, it was possible to explore responses to treated and untreated items separately. It was interesting to observe, that only GP, a person with Anomic aphasia made generalisation gains. Such analyses will not be performed at the main study, which will look at group level comparisons, rather than individual responses.

One change was made to the secondary outcome measures. It was decided to maintain the BDAE as a profiling measure, but to not use it as a secondary outcome. The BDAE is a demanding assessment requiring a long administration time. The BDAE also produces four summary scores, which would also substantially contribute to multiple comparisons, if it were to be used as a secondary outcome measure. Still the Cookie-theft picture was maintained as a secondary outcome, as it was the only discourse measure used in this study.

A change was also made in the administration of the primary outcome measure to reduce respondents' burden for participants with Global aphasia. Based on participants' CS and TT performance, who did not name any or named two items out of 260 at the baseline assessments, it was decided that when someone did not respond correctly to any of the first 65 presented pictures (25% of the total) the procedure would be terminated there.

The next chapter will present the results of the main study.

Chapter 5: Results

This chapter starts with a description of the participants of the Thales aphasia project. It presents ESFA participants' data from the different assessment points on the measures of language, functional communication and quality of life used. It then reports the main findings of this study, which aimed to:

i) Compare the efficacy on different domains of the WHO ICF framework, including quality of life, of ESFA versus a control / delayed therapy group.

ii) Compare and contrast the relative efficacy on different domains of the WHO ICF framework, including quality of life, of ESFA delivered in two different approaches - direct (individual) and combination therapy (individual and group).

5.1 Thales Aphasia Project Participants

The Thales aphasia project recruited a total of 72 participants. Randomisation was performed by a person independent to the speech and language therapy researchers, at the time of participant entry to the overall Thales project. Figure 5.1 shows the randomisation process used in the project: The 72 participants were randomised via recruitment order to the three speech and language therapy groups: direct, combination, control/delayed therapy. Initially it was planned to run two randomisation cycles of 16 participants in each group (48 per cycle x 2) to reach the 96 participants target. However, due to a clerical error 18 participants were randomised per group in the first cycle. Participant entry into the project substantially slowed towards the end of the first cycle and therefore the randomisation cycles were modified. To ensure as large a number of participants as possible could receive therapy within the time frame of the project, no more participants were allocated to the control group. Instead, three more randomisation cycles ran with 10 participants allocated to either direct or combination therapy in the second cycle, and four participants in the third and fourth cycle. As a result, 27 participants were randomised to direct speech and language therapy (18+5+2+2), 27 to combination therapy (18+5+2+2) and 18 to control/delayed therapy.

A further complicating factor for the research project, however, was that the speech and language therapy stream had additional inclusion criteria to the overall project and as a result 14 research participants were excluded from this stream after randomisation as they: a) did not meet inclusion criteria (n=12), b) declined to participate to therapy (n=1) and c) lived at another city faraway from Athens (n=1). This resulted in uneven numbers of participants in the three groups. The 58 participants who took part were therefore split in the three groups as follows: direct approach (n= 23), combination approach (n=17) and control group – delayed therapy approach (n=18). Figure 6.1 shows participant flow in the study. Participants from the delayed therapy approach were randomised to direct or combination approach for treatment after the third evaluation (8 to direct and 10 to combination).

The Thales project investigated two different therapies: ESFA and mapping. Participants were allocated to either ESFA (18 from direct, 9 from combination, 12 from control, total n= 39) or Mapping therapy (5 from direct, 8 from combination, 6 from control, total n=19) based on their performance on the BDAE. Mapping therapy results are not presented in this project. At the end of the study 22 individuals had received ESFA with direct, 14 with combination approach, and three had dropped out. One of the participants who dropped out did not complete the initial assessment process and therefore their data were excluded from further analyses (ESFA n=38). For the other two participants who started the project and subsequently dropped out, we analysed their data as per intention to treat, using the last observation carried forward method, in the therapy versus control / delayed therapy comparison. In the direct versus combination therapy comparison they were not included in the analysis as they had no data to contribute: both these participants were control group participants who did not start therapy (one dropped out and the other was excluded as he started speech language therapy privately). As a result, ESFA findings will be presented for:

I) Comparing outcomes between therapy (direct and combination, n=26) and control/delayed treatment (n=12).

II) Comparing outcomes between the two approaches, direct (n=22) versus combination (n=14).

ESFA participant characteristics are presented and comparisons are drawn between the treatment and control groups.

Thales Participants n=72 Randomisation via recruitment order									
Direct Approach n=27 (4 randomisation cycles)			Combination Approach n=27 (4 randomisation cycles)			Control / Delayed Therapy Group n=18 (1 randomisation cycle)			
Excluded from the SLTs stream n= 14 a) Not meeting inclusion criteria n= 12 b) Declined to participate n= 1 c) Lived out of the area n= 1									
SLTs Stream Participants n=58									
Direct Approach n=23			Combination Approach n=17			Control / Delayed Therapy Group n=18			
Baseline Assessment 1 (BL1) Week 1 Completed Assessment n=58									
Direct Mapping n=5	Direct ESFA n=18		Combination Mapping n=5	Combination ESFA n=9		Control Mapping n=6	Control ESFA n=12		
Baseline Assessment 2 (BL2) Week 6 Completed Assessment n=57									
Direct Mapping n=5	Direct ESFA n=18		Combination Mapping n=5	Combination ESFA n=8		Control Mapping n=6	Control ESFA n=12		
SLT Therapy Week 7 to 18						No Therapy Week 7 to 18			
Assessment 3: Post Therapy Week 19 Completed Assessment n=36						Assessment 3: BL3 Week 19 Completed Assessment n=18			
Direct Mapping Cum.=5	Direct ESFA Cum.=17 / ITT=1		Combination Mapping Cum.=5	Combination ESFA Cum.=8		Control Mapping Cum.=6	Control ESFA Cum.=12		
						Adjusted to ESFA Therapy Excluded = 18 Excluded = 1 Drop out = 4			
No Therapy Week 20-31						SLT Therapy Week 20-31			
						Direct Mapping n=5	Combination Mapping n=5	Direct ESFA n=5	Combination ESFA n=5
Assessment 4: Follow - Up Week 32 Completed Assessment n=27						Assessment 4: Post Therapy Week 32 Completed Assessment n=13			
Direct Mapping Cum.=5	Direct ESFA Cum.=18 ITT=2		Combination Mapping Cum.=5	Combination ESFA Cum.=8		Direct Mapping n=5	Combination Mapping n=5	Direct ESFA n=5	Combination ESFA n=5
Completed Assessment n=37 Mapping : Direct n=5 / Combination n=8 ESFA: Direct n=16 / Combination n=8						No Therapy Week 33 - 44 Completed Assessment n=13 Mapping: Direct n=3 ESFA: Direct n=4 / Combination ESFA n=6			
						Assessment 5: Follow - Up Week 45 Completed Assessment n=13			
						Direct Mapping n=3	Combination Mapping n=3	Direct ESFA n=4	Combination ESFA n=6
Completed Assessment n=37 Mapping : Direct n=5 / Combination n=8 ESFA: Direct n=16 / Combination n=8						Completed Assessment n=13 Mapping: Direct n=3 ESFA: Direct n=4 / Combination ESFA n=6			

5.2 ESFA Therapy versus Control/ Delayed Therapy Group

5.2.1 Participant Characteristics

Of the 38 participants who were allocated to ESFA, 26 were allocated to therapy and 12 to the control / delayed therapy group. Descriptive statistics on the participant characteristics are presented in table 5.2. The two groups were well matched in terms of their demographic and stroke related characteristics. The therapy group comprised 20 men and 6 women and the control/delayed therapy group 6 men and 6 women; this difference was not significant (Fisher's exact $p = .139$). In the therapy group 17/26 were married and in the control group 6/12; there were no significant differences between the groups in marital status [$\chi^2(3) = 1.61$, $p = .658$]. There was no significant difference in aphasia severity between the two groups, with the therapy group showing mainly severe ($n=14$) and moderate ($n=7$) aphasia and the control / delayed therapy group severe ($n=5$) and moderate ($n=4$) [$\chi^2(2) = .49$, $p = .783$]. There were no significant differences between the two groups in months' post onset [therapy ($M=36.73$, $SD=49.30$) and control ($M=16.00$, $SD=21.89$), $t(36) = -1.39$, $p = .174$]; age [therapy ($M=58.38$, $SD=11.26$) and control ($M=58.42$, $SD=11.99$), $t(36) = .01$, $p = .994$]; and years of education [therapy ($M=13.27$, $SD=3.80$) and control ($M=13.00$, $SD=4.45$), $t(36) = -.19$, $p = .849$].

Table 5.7: Participants Characteristics for ESFA Therapy versus Control / Delayed Therapy Group

Variables	Therapy Group	Control / Delayed Therapy Group
Number of Participants	26	12
Age (years)		
Mean	58.38	58.42
Standard Deviation	11.26	11.99
Range	38 – 84	44 - 79
Gender		
Male	20	6
Female	6	6
Time Post Onset (months)		
M	36.73	16.00
SD	49.30	21.89
Range	4 - 207	4 - 78
Work Status		
Full – time	11	6
Part – time	1	1
Self-employed	4	1
Unemployed	-	1
Retired due to age	8	3
Retired due to disability	2	-

Variables	Therapy Group		Control / Delayed Therapy Group
Marital Status			
Single	2		2
Married	17		6
Divorced	5		2
Widowed	2		2
Education Status (years)			
M	13.27		13.00
SD	3.80		4.45
Range	6 - 20		6 - 21
Type of Stroke			
Haemorrhagic	-		1
Ischaemic	26		11
Aphasia Type (based on BDAE)			
Broca	9		5
Wernicke	1		-
Anomic	5		1
Global	7		3
Conduction	-		2
Unclassified	4		1
Aphasia Severity (BDAE)			
Mild	5		3
Moderate	7		4
Severe	14		5

Variables	Therapy Group	Control / Delayed Therapy Group
Fluency Status (BDAE)		
Fluent	5	5
Non Fluent	21	7

5.2.2 Profiling Measure: Boston Diagnostic Aphasia Examination

The BDAE was used to classify participants according to the fluency and severity of their aphasia. BDAE data are presented in table 5.1 above. The therapy group comprised 21 non-fluent participants and 5 fluent and the control/delayed therapy group 7 non-fluent and 5 fluent; this difference was not significant (Fisher's exact $p = .235$). There was no significant difference in aphasia severity between the two groups, with the therapy group showing mainly severe ($n=14$) and moderate ($n=7$) aphasia and the control / delayed therapy group severe ($n=5$) and moderate ($n=4$) [$\chi^2(2) = .49, p = .783$]. As far as aphasia type, the therapy group had mainly Broca's ($n=9$), global ($n=7$) and anomic ($n=5$) aphasic participants and the control / delayed therapy group Broca's ($n=5$), global ($n=3$) and conduction ($n=2$) aphasic participants.

5.2.3 Results on Efficacy of ESFA Therapy versus Control / Delayed Therapy

This section will detail the results on the efficacy on different domains of the WHO ICF framework, including quality of life, of ESFA therapy versus the delayed therapy/ control group. For each outcome measure the distribution of scores at the different assessment points will be presented. Where descriptive statistics and visual inspection of the data suggested a different pattern of change between the two groups across time, mixed within-between ANOVAs were used to explore these differences statistically.

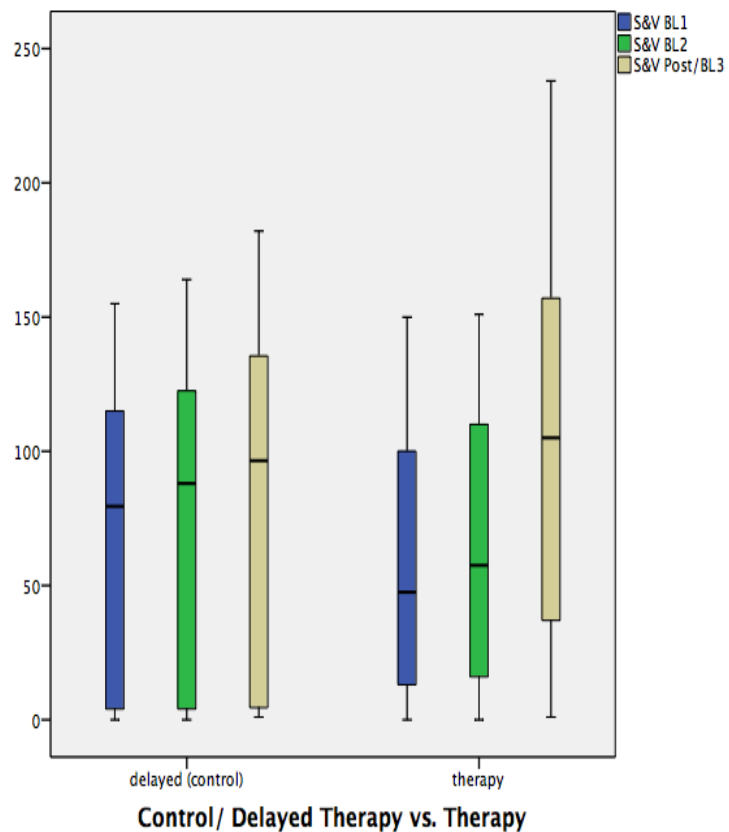
For these comparisons, assessments were completed at week 1 / baseline 1 (BL1), week 6 / baseline 2 (BL2) and week 19, which was after 12 weeks of therapy for the therapy group (Post) and after 12 weeks of no therapy / baseline 3 (BL3) for the control group.

5.2.3.1 Primary Outcome Measure: Snodgrass and Vanderwart Naming Test Therapy versus Control Group

Figure 5.8 contrasts the Snodgrass and Vanderwart measure scores of the therapy group versus the control group at the three assessment points. The box plots show the median as a dark line; the box represents the 25-75 centiles, i.e. the interquartile range; and the lines the full range of scores. Detailed descriptive statistics can be found in Appendix I, 5.2.3.1

Figure 5.8: Boxplots showing distribution of scores on Snodgrass and Vanderwart measure for therapy versus control group

Data in the boxplot suggest that medians remained relatively stable across time for the control / delayed therapy group, but increased from BL1 and BL2 to post-therapy for the therapy group. Means followed the same pattern. Scores for the control / delayed therapy group were similar (within 15 points) across the three assessment points [week 1 mean (SD) = 67.83 (57.29), week 6 mean (SD) = 74.33 (62.94), week

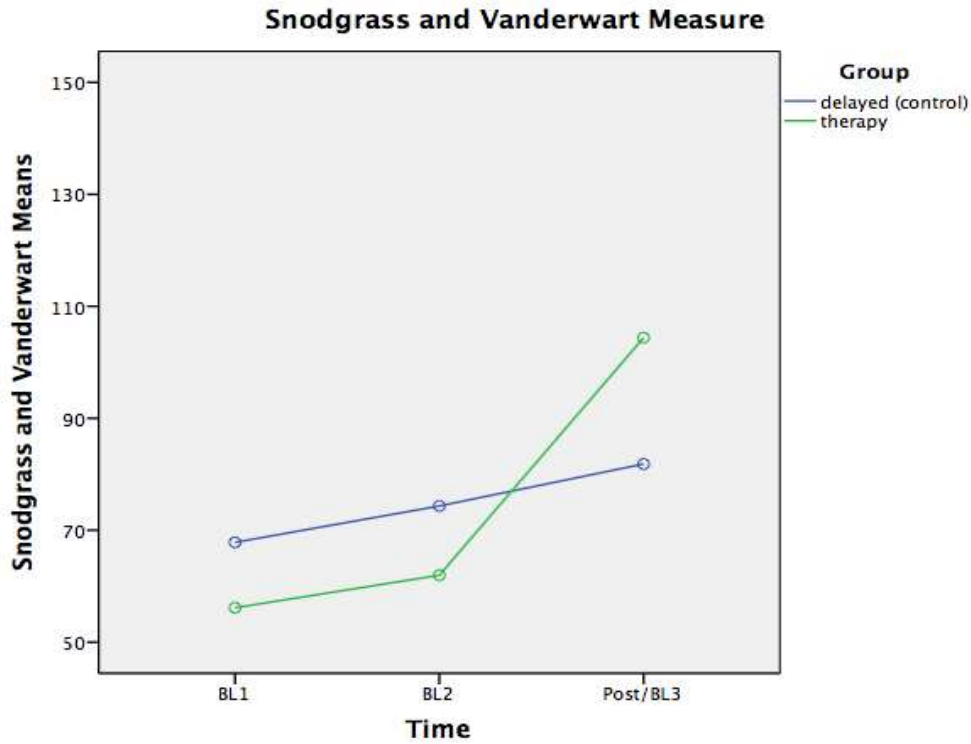


19 mean (SD) = 81.83 (69.90)]. Scores for the therapy group were similar between the two baselines but increased by >40 points from the highest baseline to the post therapy evaluation [week 1 mean (SD) = 56.15 (45.74), week 6 mean (SD) = 61.96 (49.50), week

19 mean (SD) = 104.38 (73.91)]. Scores for both groups across the three time points were normally distributed (skewness = -.02 - .33).

A two-way mixed ANOVA with two levels in the between factor (therapy vs. control) and three levels in the within factor (three assessments across time) was carried out to explore whether there was a significantly different pattern of change across time between the two groups. The effect of group was not significant $F(1, 36) = .001, p = .980$. There was a significant main effect of time, Greenhouse-Geisser $F(1.09, 39.38) = 26.04, p < .001$ with a large effect size ($\eta^2_p = .42$). Pairwise comparisons showed there was a small (mean difference = 6.15) but significant difference between BL1 and BL2 ($p = .002$) and large (mean differences = 31.12 and 24.96) significant differences between both BL1/BL2 and post-therapy/BL3 ($p < .001$). Importantly, there was also a significant interaction effect Greenhouse-Geisser $F(1.09, 39.38) = 9.56, p = .003$ with a large effect size ($\eta^2_p = .21$), whereby the therapy group improved significantly more from BL2 (week 6) [mean (SD) = 61.96 (49.50)] to post-therapy (week 19) [mean (SD) = 104.38 (73.91)] than the control group [week 6 mean (SD) = 74.33 (62.94), week 19 mean (SD) = 81.83 (69.90)] (Figure 5.9).

Figure 5.9: Mean scores of Snodgrass and Vanderwart Measure for therapy vs. control/delayed therapy group across time



5.2.3.2 Secondary Outcome Measures

The results of the secondary outcome measures are presented based on the classification of the International Classification of Functioning, Disability and Health (ICF; WHO, 2001). Firstly, body functions and structure, impairment - based level results are presented, i.e. the Boston Naming Test (BNT). Then results from outcomes tapping on the ICF activity and participation level, i.e. the American Speech and Hearing Association Functional Assessment of Communication Skills (ASHA – FACS) and Discourse scores from the BDAE Cookie Theft picture. Personal factor level results are then reported, i.e. the General Health Questionnaire (GHQ-12). Lastly, health related quality of life results are presented, i.e. the Stroke and Aphasia Quality of Life Scale-39g scale (SAQOL-39g) and the EQ-5D.

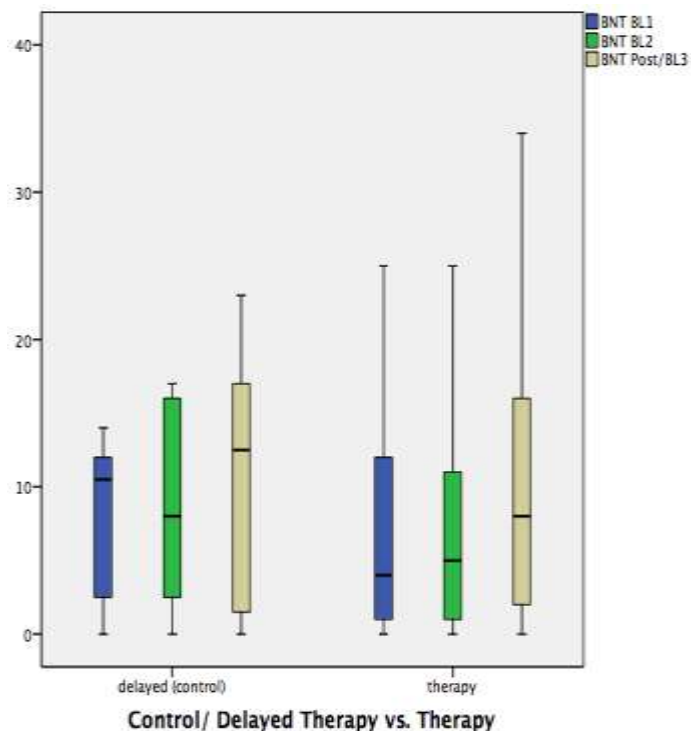
5.2.3.2.1 Body Functions and Structure - Impairment - Based Level Results

5.2.3.2.1.1 BNT Therapy versus Control Group

Figure 5.10 contrasts the BNT measure scores of the therapy group versus the control group at the three assessment points. Detailed descriptive statistics can be found in Appendix I, 5.2.3.2.1.1.

Figure 5.10: Boxplots showing distribution of scores on BNT measure for therapy versus control group

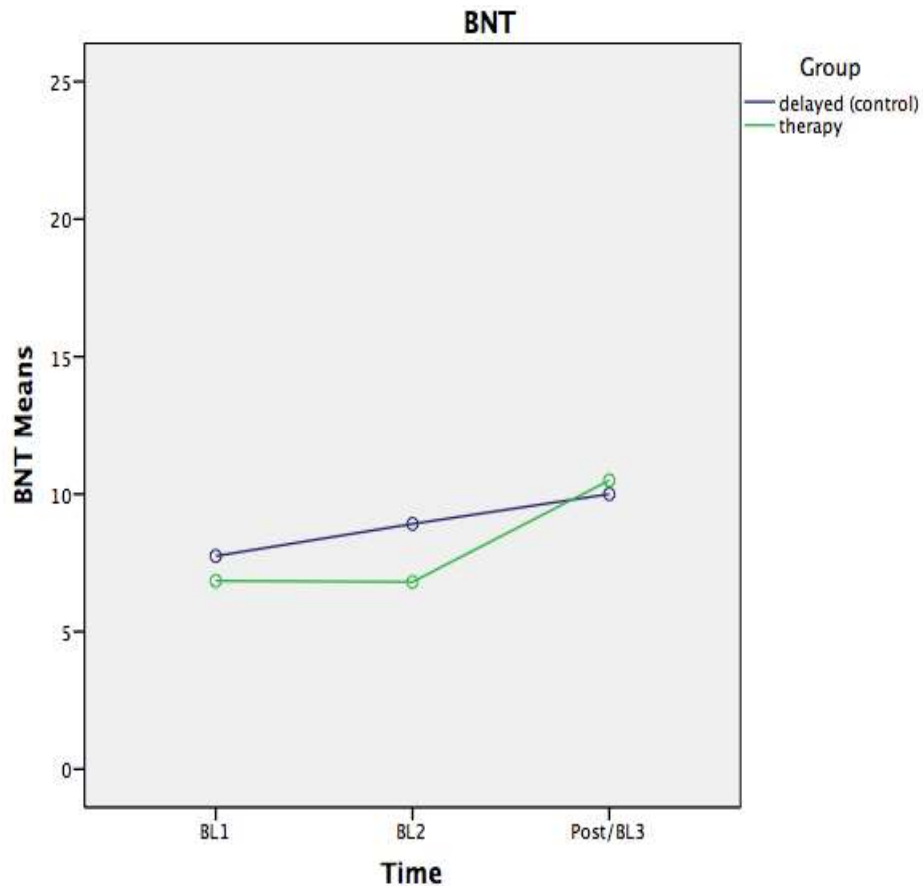
Inspection of the boxplot suggests that medians improved for both groups at the time 3 assessment. Scores were more spread out for the therapy group, which achieved higher top scores. Mean scores for the control / delayed therapy group remained stable / increased across the three assessment points by ~1.1 [week 1 mean (SD) = 7.75 (5.45), week 6



mean (SD) = 8.92 (6.87), week 19 mean (SD) = 10.00 (8.37)]. Scores for the therapy group were similar between the two baselines but increased by 3.65 points from the highest baseline to the post therapy evaluation [week 1 mean (SD) = 6.85 (7.17), week 6 mean (SD) = 6.81 (6.53), week 19 mean (SD) = 10.50 (9.84)]. Scores across the three time points were normally distributed for the delayed therapy group (skewness = -.006 – -.42) and near normally distributed for the therapy group (skewness = .97 - 1.08).

A two-way mixed ANOVA with two levels in the between factor (therapy vs. control) and three levels in the within factor (three assessments across time) was carried out to explore whether there was a significantly different pattern of change across time between the two groups. The effect of group was not significant $F(1,36) = .11, p = .743$. There was a significant main effect of time, Greenhouse - Geisser $F(1.45, 52.14) = 8.37, p = .002$ with a large effect size ($\eta^2_p = .19$). Pairwise comparisons showed there was no significant difference between BL1 and BL2 (mean difference = .56), a significant difference between BL1 and post-therapy/BL3 (mean difference = 2.95, $p = .004$) and a significant difference between BL2 and post-therapy/BL3 (mean difference = 2.39, $p = .036$). Although visual inspection of the data (Figure 5.11) suggested a sharper increase in scores for the therapy group from BL2 to post-therapy, the interaction effect was not significant, $F(1.45, 52.14) = 1.45, p = .242, \eta^2_p = .04$.

Figure 5.11: Mean scores of BNT for therapy vs. control/delayed therapy group across time



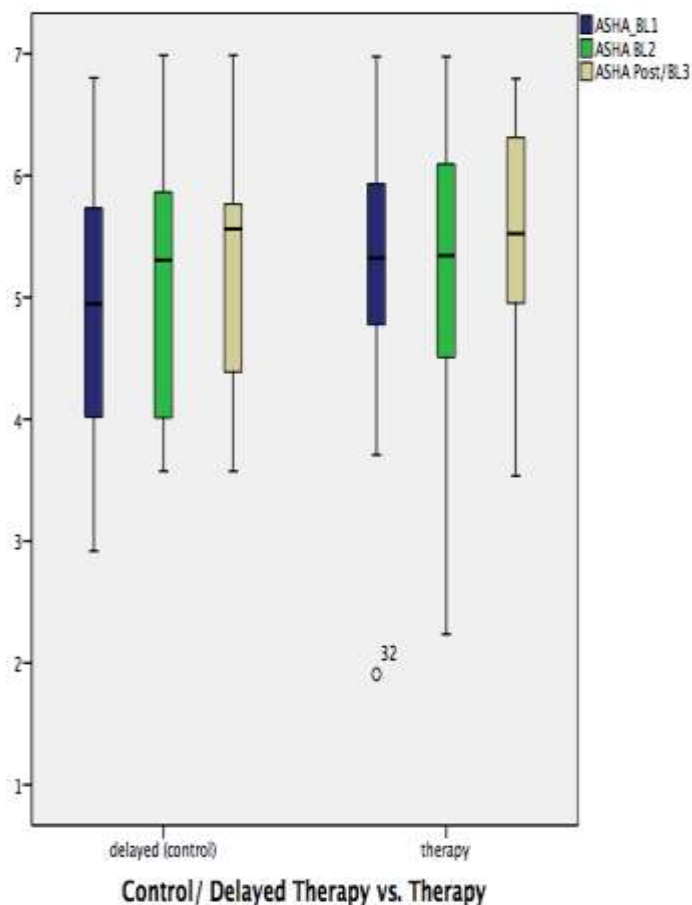
5.2.3.2.2 Activity and Participation Level Results

5.2.3.2.2.1 ASHA - FACS Therapy versus Control Group

Figure 5.12 presents the distribution of scores and medians on the ASHA-FACS, the functional communication measure. Detailed descriptive statistics can be found in Appendix I, 5.2.3.2.2.1.

Figure 5.12: Boxplots showing distribution of scores on ASHA - FACS measure of the therapy group versus the control group at the three assessment points

Medians for the control / delayed therapy groups showed a small increase across time. Medians for the therapy group showed a small increase post-therapy. Similarly, mean scores for the control / delayed therapy group showed a small increase across the three assessments [week 1 mean (SD) = 4.91 (1.19), week 6 mean (SD) = 5.13 (1.13), week 19 mean (SD) = 5.28 (1.09)], whereas mean scores for the therapy group were the same between the two baselines but



increased by .31 points from the highest baseline to the post therapy evaluation [week 1 mean (SD) = 5.24 (1.09), week 6 mean (SD) = 5.24 (1.13), week 19 mean (SD) = 5.55 (.92)]. As the boxplot illustrated, of the therapy group one participant was an outlier at

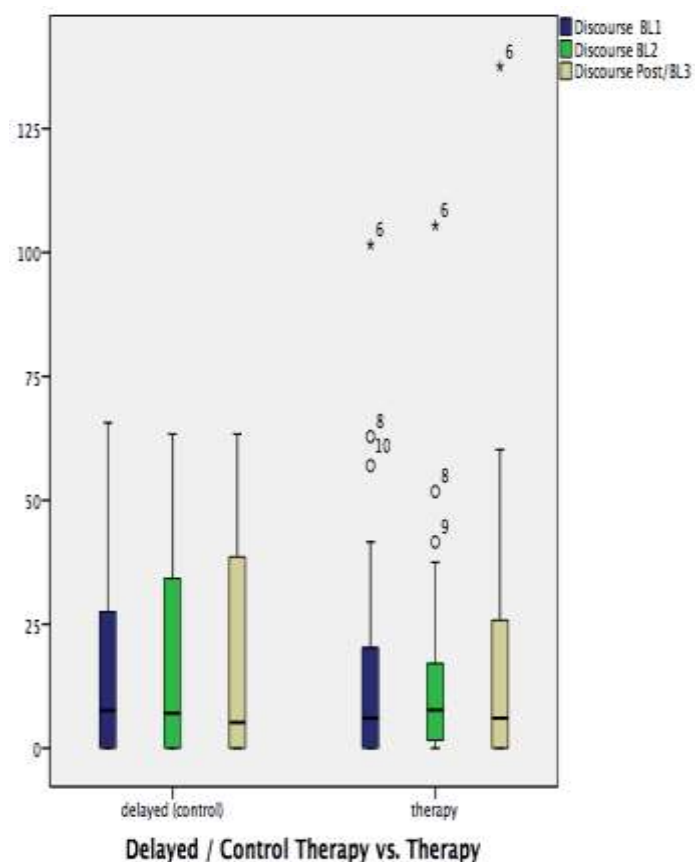
BL1. Scores for both groups across the three time points were near-normally distributed (skewness = -1.06 – .08). Based on the boxplots, the small differences in means across time and the non-parametric nature of the data, no mixed ANOVA was carried out.

5.2.3.2.2.2 Discourse “Cookie Theft” Picture Therapy versus Control Group

Figure 5.13 contrasts the discourse scores of the therapy group versus the control group at the three assessment points. Detailed descriptive statistics can be found in Appendix I, 5.2.3.2.2.2.

Figure 5.13: Discourse scores of the therapy group versus the control group at the three assessment points

Inspection of the boxplot suggested that median scores were relatively stable across time. In the therapy group two participants were outliers at BL1 and BL2 and one was an extreme outlier at all assessment points, as s/he was more than 3 box – lengths above the box. Mean scores of the delayed/ control therapy group were stable during the three assessment points [week 1: mean (SD) = 17.65 (24.47), week 6: mean (SD) = 19.16 (23.81), week 19: mean (SD)=18.64 (22.47)], whereas scores for the therapy group were



stable for the baselines but a small increase was found at post therapy evaluation [week 1: mean (SD) = 16.35 (24.62), week 6: mean (SD) = 15.22 (23.11), week 19: mean (SD)=18.14 (30.04)]. Scores were highly skewed across time points for the therapy group (skewness = 2.20 – 2.85) and skewed at BL1 and BL2 for the control / delayed treatment group (skewness = 1.09 – 1.39). Based on the boxplots, the small differences in means across time and the non-parametric nature of the data, no mixed ANOVA was carried out.

5.2.3.2.3 Personal Factor Level Results

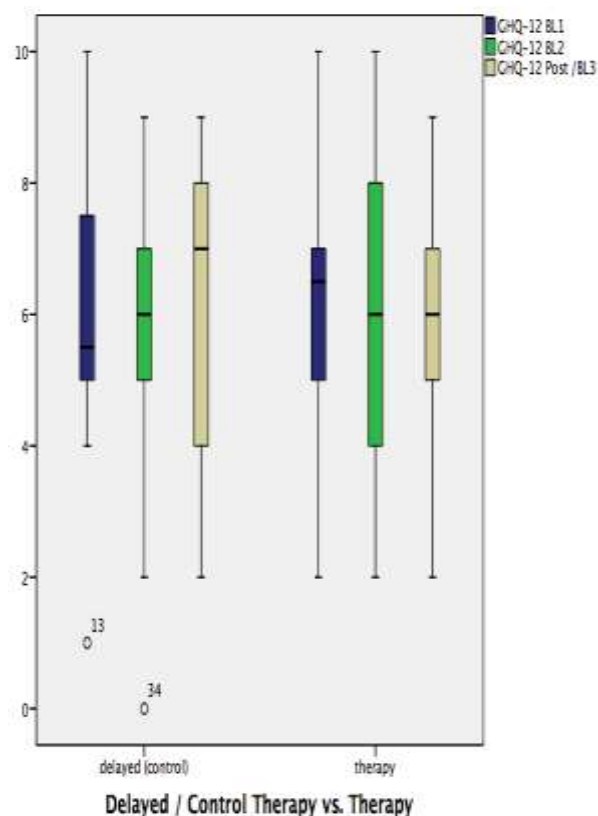
5.2.3.2.3.1 GHQ-12 Therapy versus Control Group

Figure 5.14 contrasts the GHQ-12 scores of the therapy group versus the control group at the three assessment points. Detailed descriptive statistics can be found in Appendix I, 5.2.3.2.3.1.

Figure 5.14: GHQ-12 scores of the therapy group versus the control group at the three assessment points

Looking at the boxplot, though the median for the delayed therapy / control group seemed to deteriorate from the first two assessment points to the third, this difference seems to be inflated by the presence of outliers in the first two assessment points. Delayed therapy / control group means were relatively stable across the assessment points [week 1 mean (SD) = 6.00 (2.41), week 6 mean (SD) = 5.50 (2.39), week 19 mean (SD) = 6.17 (2.17)]. Therapy group scores followed the same pattern

[week 1 mean (SD) = 6.27 (1.93), week 6 mean (SD) = 6.04 (2.44), week 19 mean (SD) = 6.12 (1.66)]. Scores for both groups across the three time points were normally distributed (skewness = -.05 - -.64) with the exception of BL2 scores for the control / delayed treatment group (skewness = -1.24). Based on the boxplots and the mean scores, no mixed ANOVA was carried out, as scores between the groups across time were similar.



5.2.3.2.4 Quality of Life Level Results

5.2.3.2.4.1 SAQOL- 39g Therapy versus Control Group

The SAQOL-39g consists from three domains - physical, psychosocial and communication - and an overall health related quality of life score.

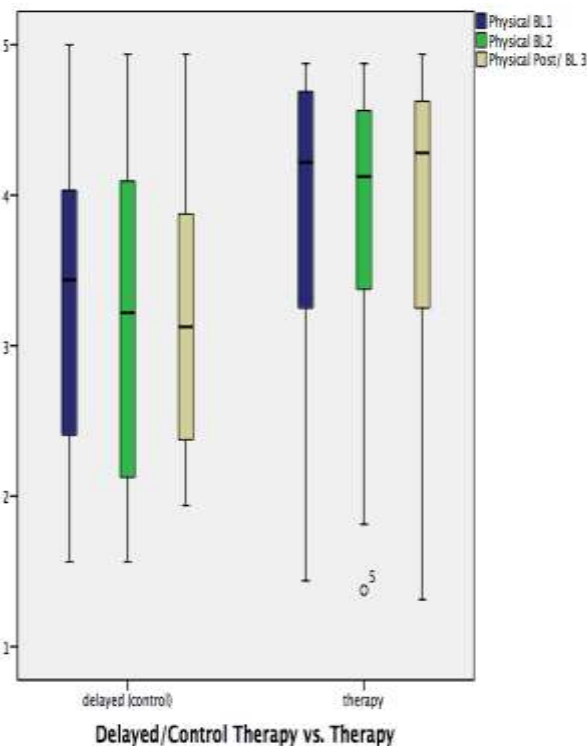
I) Physical Domain

Figure 5.15 contrasts the physical domain scores of the therapy group versus the control group at the three assessment points. Detailed descriptive statistics can be found in Appendix I, 5.2.3.2.4.1.I

Figure 5.15: SAQOL-39g physical domain scores of the therapy group versus the control group at the three assessment points

As expected for this domain, scores remained similar for both groups across all assessment points [the delayed therapy / control group- week 1 mean (SD) = 3.31 (1.02), week 6 mean (SD) = 3.20 (1.12), week 19 mean (SD) = 3.17 (.95) and the therapy group- week 1 mean (SD) = 3.80 (1.01), week 6 mean (SD) = 3.79 (.98), week 19 mean (SD) = 3.89 (.92). An outlier was found at the second baseline of the therapy group. Scores were

normally distributed with the exception of the post-therapy scores for the therapy group (skewness = -1.10). No further statistical analysis was undertaken, as the visual inspection



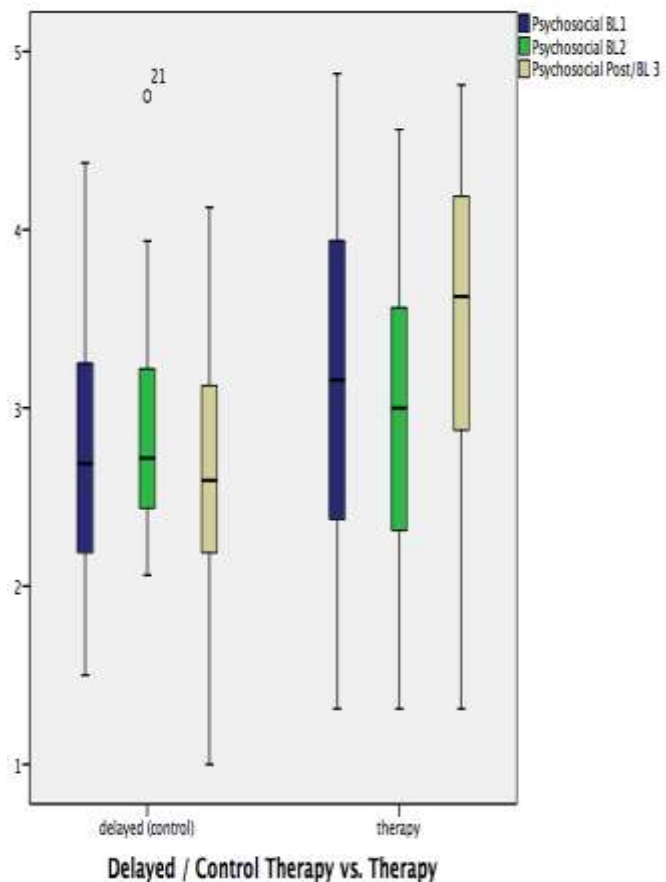
of the data and the mean scores did not suggest a different pattern of change between the two groups across time.

II) Psychosocial Domain

Figure 5.16 contrasts the psychosocial domain scores of the therapy group versus the control group at the three assessment points. Detailed descriptive statistics can be found in Appendix I, 5.2.3.2.4.1.II.

Figure 5.16: SAQOL-39g psychosocial domain scores of the therapy group versus the control group at the three assessment points

Medians were similar between the two first assessment points for both groups. At the third assessment point, there was a slight drop for the delayed therapy / control group and an improvement for the therapy group. Delayed therapy / control group mean scores increased from BL1 to BL2 but dropped at BL3 [week 1 mean (SD) = 2.75 (.78), week 6 mean (SD) = 2.95 (.77), week 19 mean (SD) = 2.63 (.82)]. There was an outlier at the second baseline assessment point for the delayed/ control therapy group. Therapy group scores decreased from BL1

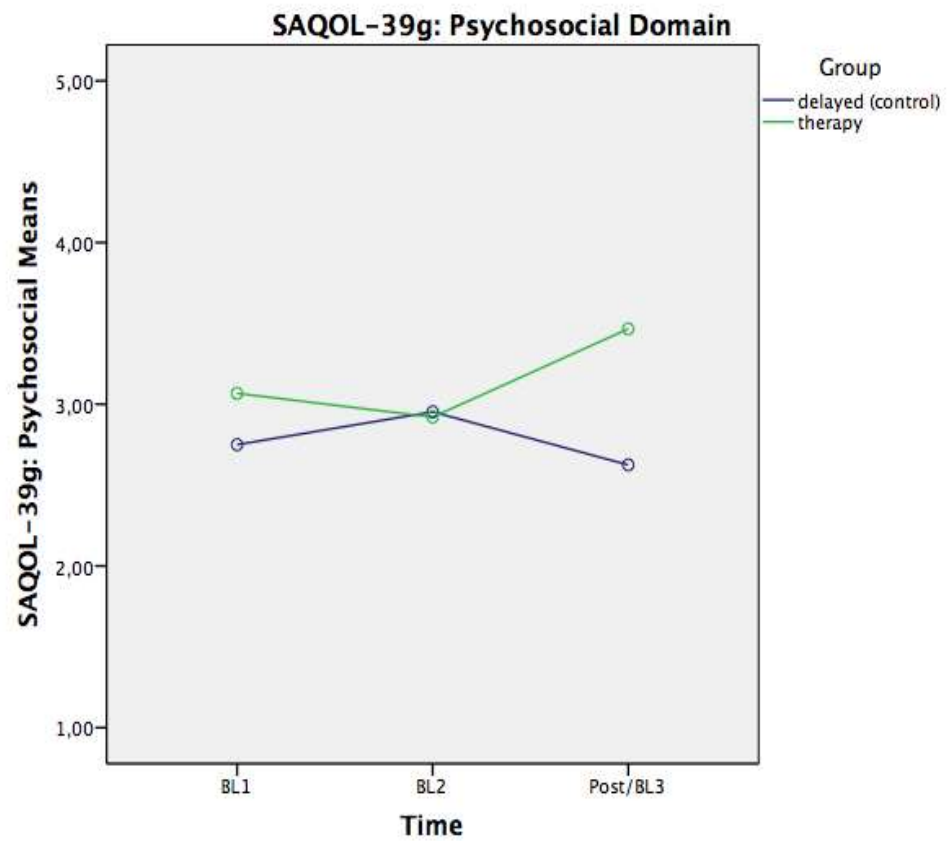


to BL2 and increased post therapy [week 1 mean (SD) = 3.07 (1.04), week 6 mean (SD)

= 2.92 (.98), week 19 mean (SD)= 3.47(.93)]. Scores for both groups were normally distributed with the exception of the second baseline score for the delayed therapy / control group (skewness = 1.27).

A two-way mixed ANOVA with two levels in the between factor (therapy vs. control) and three levels in the within factor (three assessments across time) was carried out to explore whether there was a significantly different pattern of change across time between the two groups. The effect of group was not significant $F(1,36) = 1.78, p = .191$. The effect of time was not a significant, Greenhouse - Geisser $F(1.72,61.87) = .54, p = .558$ with small effect size ($\eta^2_p = .015$). A significant interaction effect was found with $F(1.72,61.87) = 5.00, p = .013$ with a medium effect size ($\eta^2_p = .12$). The scores were relatively stable across baselines, and the therapy group improved from BL2 [week 6, mean (SD) = 2.92 (.98)] to post - therapy [week 19, mean (SD) = 3.47(.93)], whereas the control group's scores showed a decline [week 6, mean (SD) = 2.95 (.77)], to week 19, mean (SD) = 2.63 (.82)] (Figure 5.17).

Figure 5.17: Mean scores of psychosocial domain for therapy vs. control/delayed therapy group across time



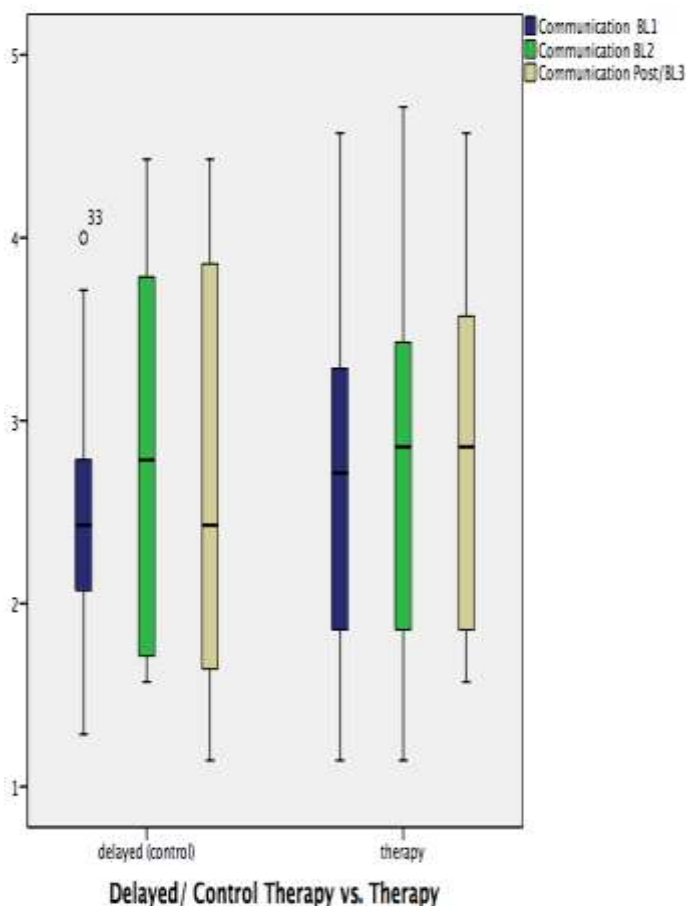
III) Communication Domain

Figure 5.18 contrasts the communication domain scores of the therapy group versus the control group at the three assessment points. Detailed descriptive statistics can be found in Appendix I, 5.2.3.2.4.1.III.

Figure 5.18: SAQOL-39g communication domain scores of the therapy group versus the control group at the three assessment points

Median scores increased from BL1 to BL2. They then dropped for the delayed therapy / control group and remained stable for the therapy group. Delayed therapy / control group mean scores showed an increase from BL1 to BL2 and then they decreased [week 1 mean (SD) = 2.52 (.78), week 6 mean (SD) = 2.83 (1.07), week 19 mean (SD) = 2.65 (1.18)]. Therapy group mean scores increased across all assessment points by a small degree [week 1 mean (SD) = 2.77 (.90),

week 6 mean (SD) = 2.82 (.90), week 19 mean (SD) = 2.86 (.91)]. An outlier was found at the first baseline of the control group. Scores for both groups across the three time points were normally distributed (skewness = .12 – .43). As the visual inspection of the data and the mean scores across time did not suggest a different pattern of change between the two groups across time, no further statistical analysis was undertaken.

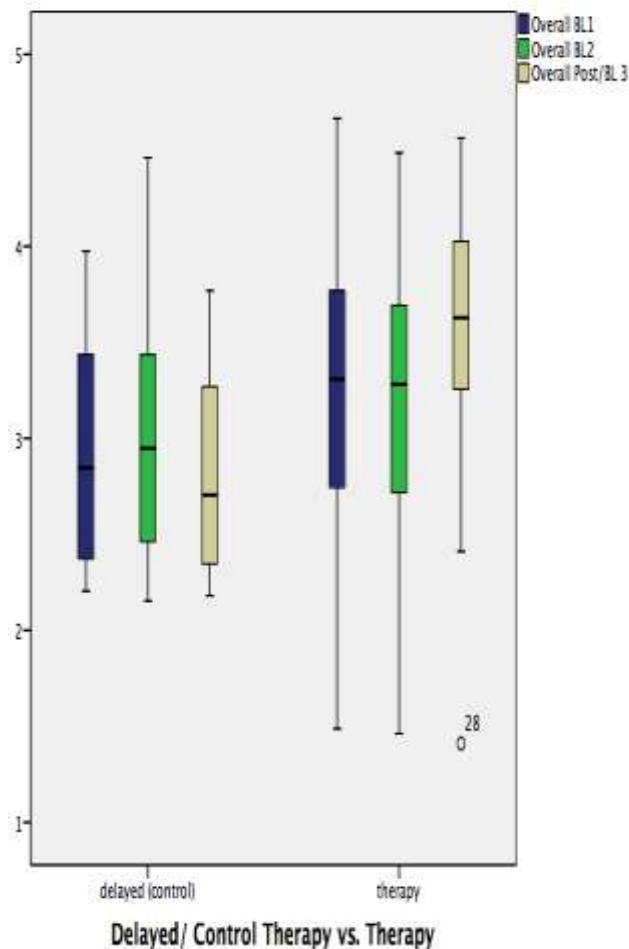


IV) Overall SAQOL-39 score

Figure 5.19 contrasts the overall domain scores of the therapy group versus the control group at the three assessment points. Detailed descriptive statistics can be found in Appendix I, 5.2.3.2.4.1. IV.

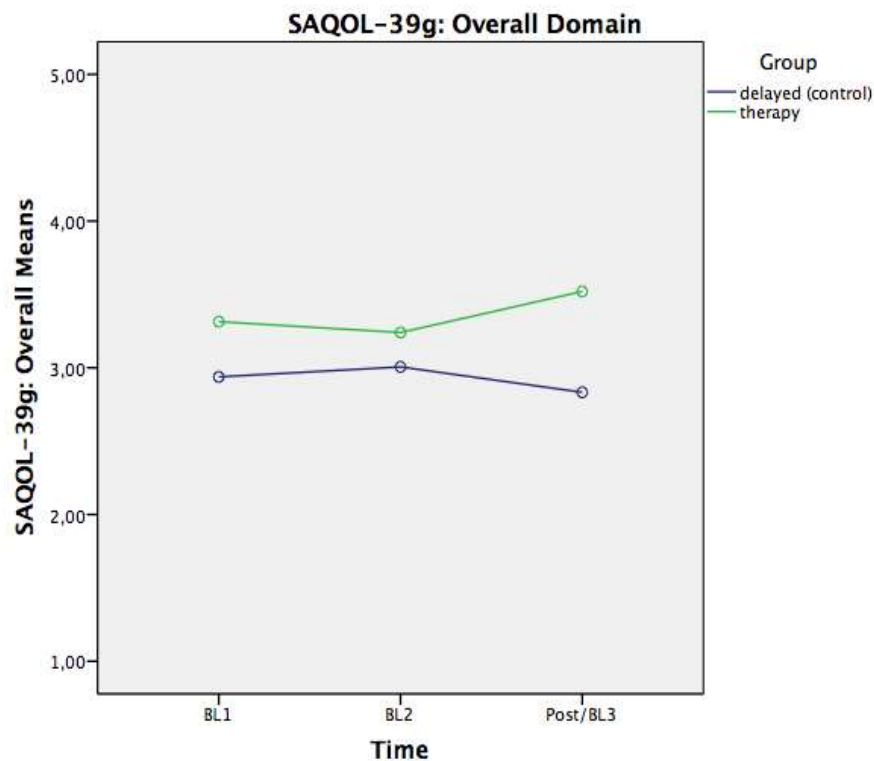
Figure 5.19: SAQOL-39g overall scores of the therapy group versus the control group at the three assessment points

Inspection of the boxplot suggests that after a stable performance across the first two assessment points for both groups, the median of the delayed therapy /control group decreased, whereas the median of the therapy group increased, despite a low outlier. The mean scores followed a similar pattern: delayed therapy / control group mean scores week 1 mean (SD) = 2.94 (.60), week 6 mean (SD) = 3.01 (.69), week 19 mean (SD) = 2.83 (.54)]. Therapy group mean week 1 mean (SD) = 3.31 (.75), week 6 mean (SD) = 3.24 (.73), week 19 mean (SD)= 3.52 (.72)]. Scores for both groups across the three time points were normally distributed with the exception of the post-therapy assessment for the therapy group (skewness = -1.05).



A two-way mixed ANOVA with two levels in the between factor (therapy vs. control) and three levels in the within factor (three assessments across time) was carried out to explore whether there was a significantly different pattern of change across time between the two groups. The effect of group was not significant $F(1,36) = 3.64, p = .065$. The main effect of time was not significant, $F(2, 72) = .30, p = .740$, with small effect size ($\eta^2_p = .008$). A significant interaction effect was found with $F(2, 72) = 4.47, p = .015$, with a medium effect size ($\eta^2_p = .11$), whereby the therapy group improved from BL2 [week 6, mean (SD) = 3.24 (.73)] to post - therapy [week 19, mean (SD) = 3.52 (.72)] and the control group slightly deteriorated [week 6, mean (SD) = 3.01 (.69)], week 19 mean (SD) = 2.83 (.54)] (Figure 5.20).

Figure 5.20: Mean scores of overall domain for therapy vs. control/delayed therapy group across time

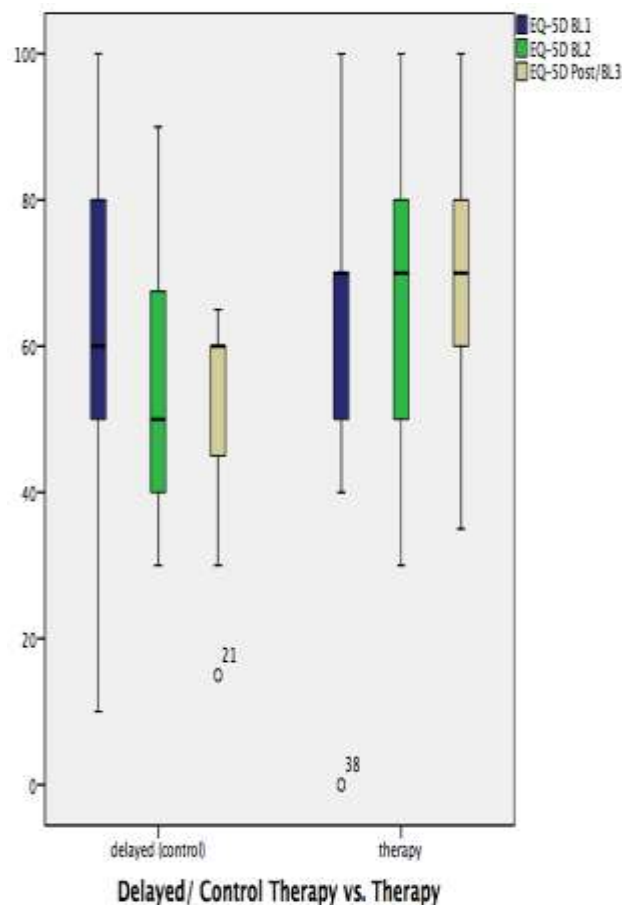


5.2.3.2.4.2 EQ-5D Therapy versus Control Group

Figure 5.21 contrasts the EQ-5D visual analogue scale (VAS) scores of the therapy group versus the control group at the three assessment points. Detailed descriptive statistics can be found in Appendix I, 5.2.3.2.4.2.

Figure 5.21: EQ-5D visual analogue scale (VAS) scores of the therapy group versus the control group at the three assessment points

Medians for the therapy group were relatively stable, though most scores were lower at BL1 than post-therapy. Medians for the delayed therapy / control group were similar at assessment 1 and 3 and lower at assessment 2; and the overall distribution of scores varied across the assessment points. Mean scores of the delayed/control therapy group dropped by 10 points (0-100 scale) across the assessment times [week 1: mean (SD) = 60.83 (23.53), week 6: mean (SD) = 55.42 (20.61), week 19: mean (SD)=

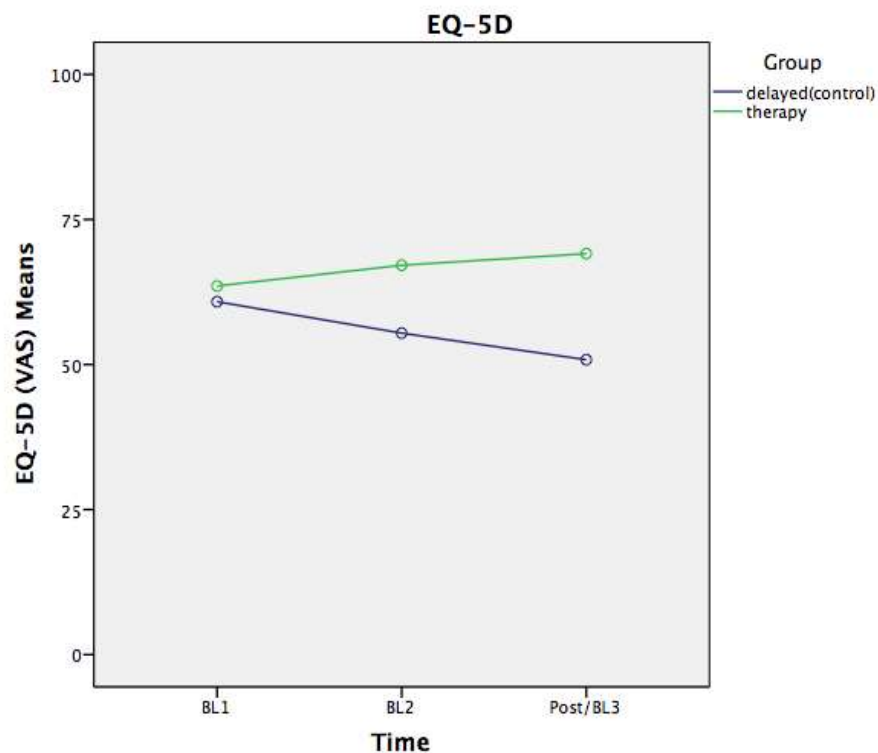


50.83(15.20)], whereas the scores of the therapy group remained relatively stable (within 5 points), with a slight upward trend [week 1: mean (SD) = 63.54 (19.35), week 6: mean (SD) = 67.12 (16.62), week 19: mean (SD)= 69.12(15.59)]. There was one outlier at the

third assessment of the delayed/ control therapy group and at the first baseline of the therapy group. Scores were not normally distributed for the delayed therapy group at assessment three (skewness = -1.52) and for the therapy group at assessment one (skewness = -1.26).

A two-way mixed ANOVA with two levels in the between factor (therapy vs. control) and three levels in the within factor (three assessments across time) was carried out to explore whether there was a significantly different pattern of change across time between the two groups. The effect of group was significant $F(1,36) = 4.40, p = .043$, with a medium effect size ($\eta^2p = .11$). There was not a significant main effect of time, $F(2,72) = .25, p = .780$ with very small effect size ($\eta^2p = .007$). The interaction effect was not significant $F(1,72) = 3.08, p = .052$; the effect size was medium ($\eta^2p = .08$). (Figure 5.22).

Figure 5.22: Mean scores of the EQ visual analogue scale (VAS) for therapy vs. control/delayed therapy group across time



5.2.4 Summary of comparisons between therapy and control and adjusting for multiple comparisons

Five mixed ANOVAs were carried out to compare outcomes between the therapy group (n= 26) and the control / delayed therapy group (n = 12). The outcomes of five measures (ASHA – FACS, Discourse analysis, GHQ-12, Physical and Communication domain of SAQOL-39g) were not analysed with mixed ANOVAs, as there was no evidence of a substantial difference in means and a different pattern of change across time between the groups. Adjusting for multiple comparisons for the originally planned comparisons (10) with a Bonferroni correction ($0.05 / 10 = .005$), the following differences remained significant. There was a significant main effect of time ($p < .001$) and a significant interaction effect ($p = .003$) on the main outcome measure of naming the Snodgrass and Vanderwart pictures, whereby the therapy group improved significantly more from BL2 to post-therapy than the control group. There was a significant main effect of time for the BNT ($p = .002$), with the significant difference between the firsts two baselines and BL3/post therapy. Though the graph of the means suggested a sharper increase for the therapy group, the interaction effect was not significant. Lastly, there was an interaction effect, which did not remain significant after adjusting for multiple comparisons, for the SAQOL-39g psychosocial domain ($p = .013$) and the overall SAQOL-39g score ($p = .015$), with only the therapy group improving with therapy.

5.3 ESFA Direct versus Combination Approach

5.3.1 Participant Characteristics

Of the 36 participants who received ESFA, 22 had direct and 14 combination therapy. Descriptive statistics on the participant characteristics are presented in table 5.2. The two groups were well matched in terms of their demographic and stroke related characteristics. The direct approach comprised 16 men and 6 women and the combination approach 8 men and 6 women; this difference was not significant (Fisher's exact $p = .471$). In the direct approach 16/22 were married and in the combination approach 5/14; there were no significant differences between the groups in marital status [$\chi^2(3) = 5.39$, $p = .145$]. There was no significant difference in aphasia severity between the two groups, with the direct approach showing mainly severe ($n=12$) and moderate ($n=6$) aphasia and the combination severe ($n=6$) and moderate ($n=4$) [$\chi^2(2) = .66$, $p = .721$]. There were no significant differences between the two groups in months' post onset [direct ($M=30.55$, $SD=45.99$) and combination ($M=33.29$, $SD=42.68$) approach; $t(34) = .179$, $p = .859$]; age [direct ($M=58.23$, $SD=11.45$) and combination ($M=58.36$, $SD=11.67$) approach; $t(34) = .033$, $p = .974$]; and years of education [direct ($M=12.55$, $SD=4.34$) and combination ($M=13.50$, $SD=2.77$) approach; $t(34) = .732$, $p = .469$].

Table 5.8: Participants Characteristics for ESFA Direct versus Combination Approach

Variables	Direct Approach	Combination Approach
Number of Participants	22	14
Age (years)		
M	58.23	58.36
SD	11.45	11.67
Range	38 – 84	40 - 79
Gender		
Male	16	8
Female	6	6
Time Post Onset (months)		
M	30.55	33.29
SD	45.99	42.68
Range	4 - 207	4 - 127
Work Status		
Full - time	10	6
Part - time	1	-
Freelance	4	1
Unemployed	-	1
Retired due to age	5	6
Retired due to disability	2	-

Variables	Direct Approach	Combination Approach
Marital Status		
Free	1	3
Married	16	5
Divorced	3	4
Widowed	2	3
Education Status (years)		
M	12.55	13.50
SD	4.34	2.77
Range	6 - 20	7 - 17
Type of Stroke		
Haemorrhagic	-	-
Ischaemic	22	14
Aphasia Type (based on BDAE)		
	8	6
Broca	-	1
Wernicke	5	1
Anomic	6	3
Global	-	1
Conduction	3	2
Unclassified		

Variables	Direct Approach	Combination Approach
Aphasia Severity (based on BDAE)		
Mild	4	4
Moderate	6	4
Severe	12	6
Fluency Status		
Fluent	5	5
Non-Fluent	17	9

5.3.2 Profiling Measure: Boston Diagnostic Aphasia Examination

The BDAE was used to classify participants according to the type, the fluency and severity of their aphasia. BDAE data are presented in table 6.2 above. The direct approach comprised 18 non-fluent participants and 4 fluent and the combination approach 9 non-fluent and 5 fluent; this difference was not significant (Fisher's exact $p = .267$). There was no significant difference in aphasia severity between the two groups, with the direct approach showing mainly severe ($n=12$) and moderate aphasia ($n=6$) and the combination severe ($n=6$) and moderate aphasia ($n=4$) [$\chi^2(2) = .66$, $p = .721$]. In terms of aphasia type between the two groups, the direct approach had mainly participants with Broca's ($n=8$), global ($n=6$) and anomic aphasia ($n=5$), and the combination Broca's ($n=6$) and global ($n=3$) aphasia.

5.3.3 Results on Efficacy of ESFA Direct versus Combination Approach

This section will detail the results on the efficacy on different domains of the WHO ICF framework, including quality of life, of ESFA direct versus combination approach. For each outcome measure the distribution of scores at the different assessment points will be presented. Where descriptive statistics and visual inspection of the data suggested a different pattern of change between the two groups across time, mixed within-between ANOVAs were used to explore these differences statistically.

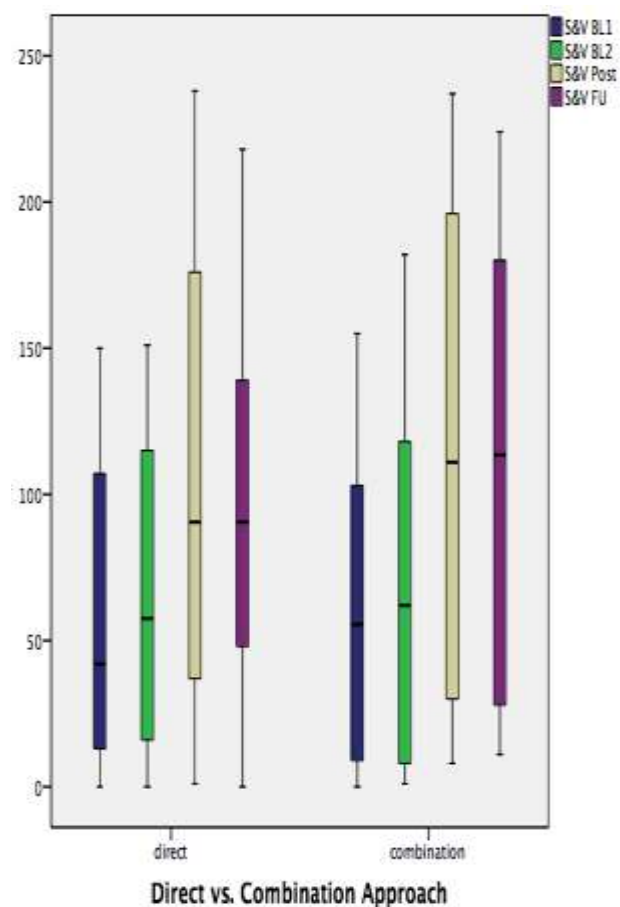
For these comparisons, assessments were completed at baseline 1 (BL1) (week 1 for those in the immediate group (IG); week 6 for those in the control group (CG)), baseline 2 (BL2) (week 6 for IG; week 19 for CG), post – therapy (week 19 for IG; week 32 for CG), which was after 12 weeks of therapy, and follow – up (week 32 for IG; week 45 for CG), which was a follow – up assessment following a period of no intervention 12 weeks post therapy.

5.3.3.1 Primary Outcome Measure: Snodgrass and Vanderwart Naming Test Direct versus Combination Approach

Figure 5.23 contrasts the Snodgrass and Vanderwart measure scores of the direct versus the combination approach at the four assessment points. The box plots show the median as a dark line; the box represents the 25-75 centiles, i.e. the interquartile range; and the lines the full range of scores. Detailed descriptive statistics can be found in Appendix I, 5.3.3.1.

Figure 5.23: Boxplots showing distribution of scores on Snodgrass and Vanderwart measure for direct versus combination approach

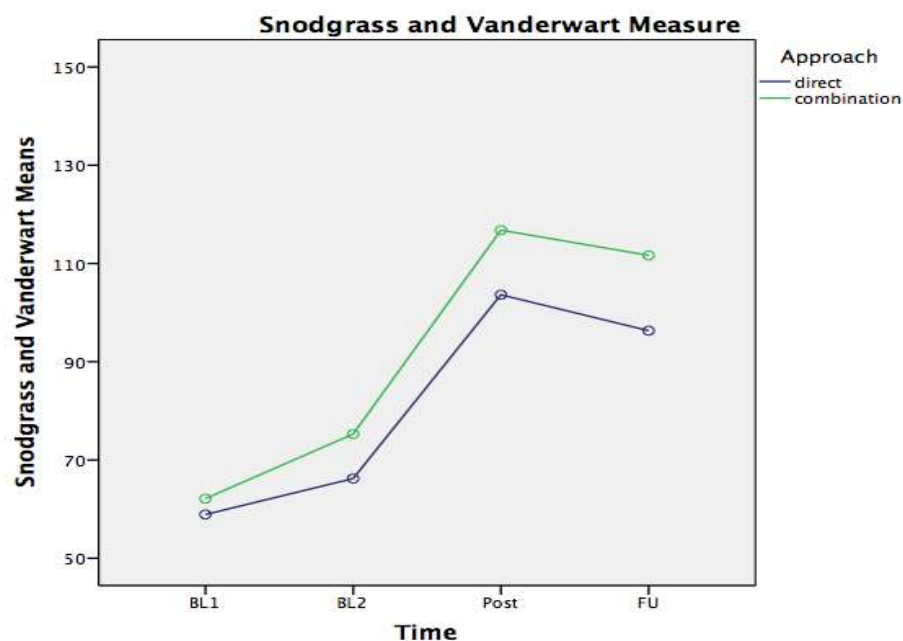
Medians demonstrated an improvement in scores for both groups at post-therapy, which was maintained at follow up. Mean scores for both approaches were similar between the two baselines, they increased by about 40 points from the highest baseline to the post therapy evaluation and increased by about 30 points from the highest baseline to the follow up assessment. The combination approach showed a bigger increase after therapy but maintenance was higher from post therapy to follow up for the direct approach group [direct BL1 mean (SD) = 58.91 (50.14), BL2 mean (SD) = 66.23 (53.95), post mean (SD) = 103.64 (77.01), follow -up mean (SD) = 96.32 (68.49) and combination (BL1 mean (SD) = 62.14 (49.67), BL2 mean (SD) = 75.29 (62.64), post



mean (SD) = 116.79 (79.45), follow-up mean (SD)=111.64 (76.90)]. Scores for both groups across the four time points were normally distributed (skewness = .11 - .41).

A two-way mixed ANOVA with two levels in the between factor (direct vs. combination) and four levels in the within factor (four assessments across time) was carried out to explore whether there was a significantly different pattern of change across time between the two groups. The effect of group was not significant $F(1,34) = .23, p = .631$. There was a significant main effect of time, Greenhouse-Geisser $F(1.90, 64.53) = 32.95, p < .001$ with large effect size ($\eta^2_p = .49$). Pairwise comparisons showed there was a small but significant difference between BL1 and BL2 (mean difference = 10.23, $p = .003$), large significant differences between BL1 to post-therapy and BL1 to follow up (mean differences = 49.69 and 43.46, $ps < .001$), large significant differences between BL2 to post – therapy and follow – up (mean differences= 39.46 and 33.22, $ps < .001$). The difference between post – therapy and follow- up (mean difference= 6.23) was not significant ($p=1$). The interaction effect was not significant Greenhouse-Geisser $F(1.90, 64.53) = .39, p = .668$ (Figure 5.24).

Figure 5.24: Mean scores of Snodgrass and Vanderwart Measure for direct vs. combination approach



5.3.3.2 Secondary Outcome Measures

The results of the secondary outcome measures are presented based on the classification of the International Classification of Functioning, Disability and Health (ICF; WHO, 2001). Firstly, body functions and structure, impairment - based level result is presented, i.e. the Boston Naming Test (BNT). Then results from outcomes tapping on the ICF activity and participation level, i.e. the American Speech and Hearing Association Functional Assessment of Communication Skills (ASHA – FACS) and Discourse scores from the BDAE Cookie Theft picture. Personal factor level results are reported, i.e. the General Health Questionnaire (GHQ-12). Lastly, health related quality of life results are presented, i.e. the Stroke and Aphasia Quality of Life Scale-39g scale (SAQOL-39g) and the EQ-5D.

5.3.3.2.1 Body Functions and Structure - Impairment - Based Level Results

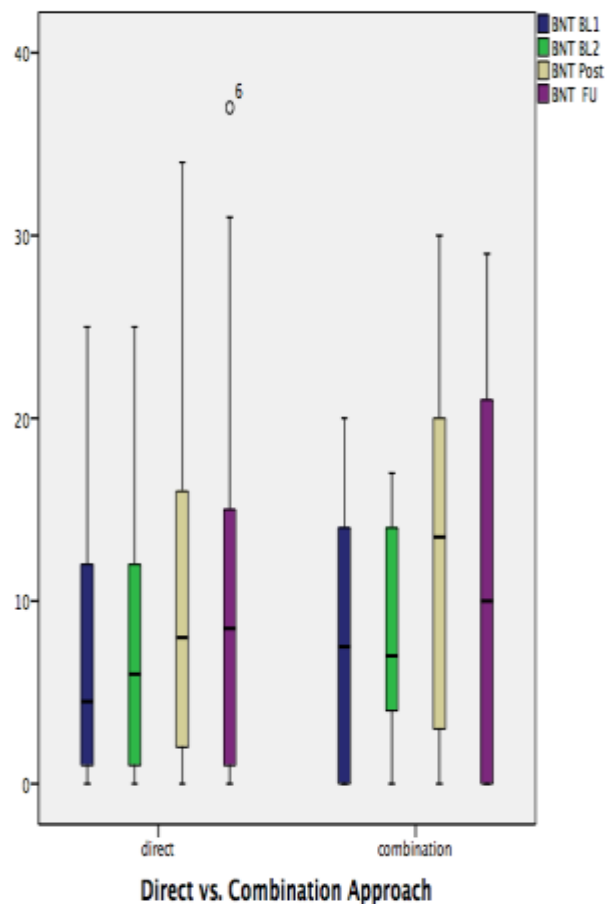
5.3.3.2.1.1 BNT Direct versus Combination Approach

Figure 5.25 contrasts the BNT measure scores of the direct versus the combination approach at the four assessment points. Detailed descriptive statistics can be found in Appendix I, 5.3.3.2.1.1.

Figure 5.25: Boxplots showing distribution of scores on BNT measure for direct vs. combination approach

Medians demonstrated a gradual increase for the direct approach but a sharp increase for the combination approach from pre to post therapy and a small drop at follow up. Mean scores remained stable for both approaches between the two baselines [direct BL1 mean (SD) = 6.95 (6.74), BL2 mean (SD) = 7.41 (7.22) and for combination BL1 mean (SD) = 7.50 (6.98), BL2 mean (SD) = 8.00 (6.21)]. Scores increased for both groups after therapy [direct post mean (SD) = 10.77 (10.80) and combination post mean (SD) = 13.14 (10.28)], with scores of the combination approach

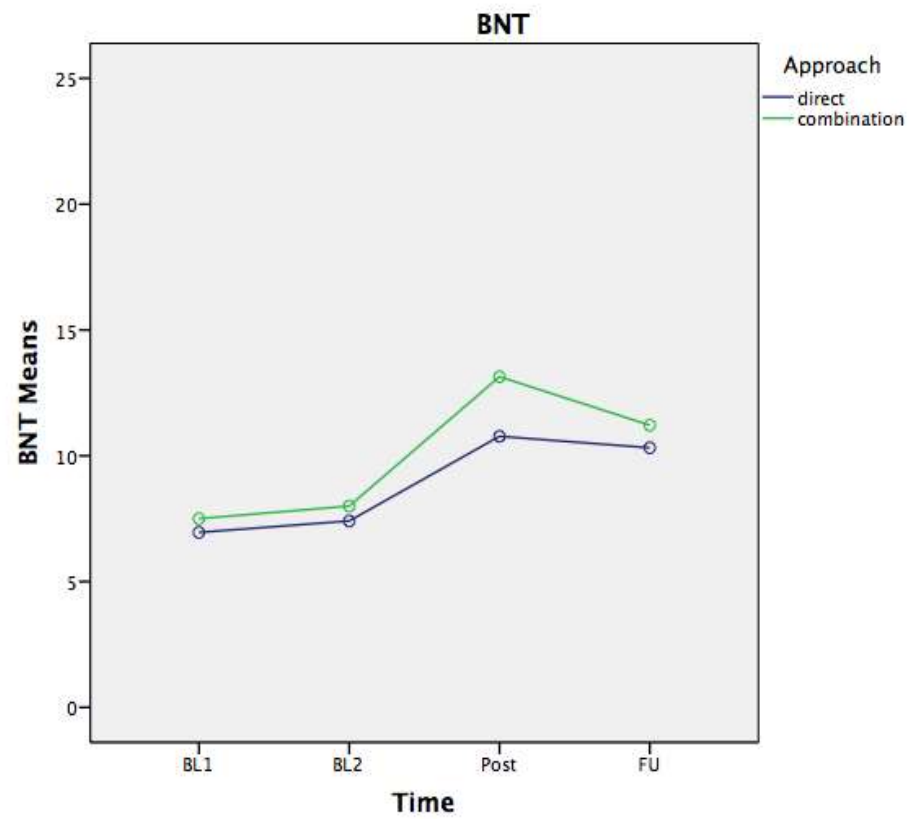
increasing slightly more (5.14 points) than the direct approach (3.36 points) from the highest baseline to the post therapy evaluation. Scores at the follow-up evaluation were higher than at baselines [direct follow-up mean (SD) = 10.32 (10.27) and combination



follow-up mean (SD) = 11.21 (10.14)]. There was one outlier at the follow –up assessment of the direct approach group. Scores were normally distributed for the combination approach across the four time points (skewness = .20 - .33) and near-normally distributed for the direct approach (skewness = .80 – 1.18).

A two-way mixed ANOVA with two levels in the between factor (direct vs. combination) and four levels in the within factor (four assessments across time) was carried out to explore whether there was a significantly different pattern of change across time between the two groups. The effect of group was not significant $F(1,34) = .15, p = .698$. There was a significant main effect of time, Greenhouse - Geisser $F(1.91, 64.77) = 13.88, p < .001$ with large effect size ($\eta^2_p = .29$). Pairwise comparisons showed there was no significant difference between BL1 and BL2 (mean difference = .48), a significant difference between BL1 to post-therapy and follow-up (mean differences = 4.73 and 3.54, $p < .001$ and $p = .003$ respectively), a significant difference between BL2 and post-therapy and follow up (mean differences = 4.25 and 3.06, $p = .001$ and $p = .018$ respectively) and no significant difference between post – therapy and follow up (mean difference = 1.19 and $p = .64$). The interaction effect was not significant, Greenhouse - Geisser $F(1.91, 64.77) = .48, p = .611$ (Figure 5.26).

Figure 5.26: Mean scores of BNT for direct vs. combination approach



5.3.3.2.2 Activity and Participation Level Results

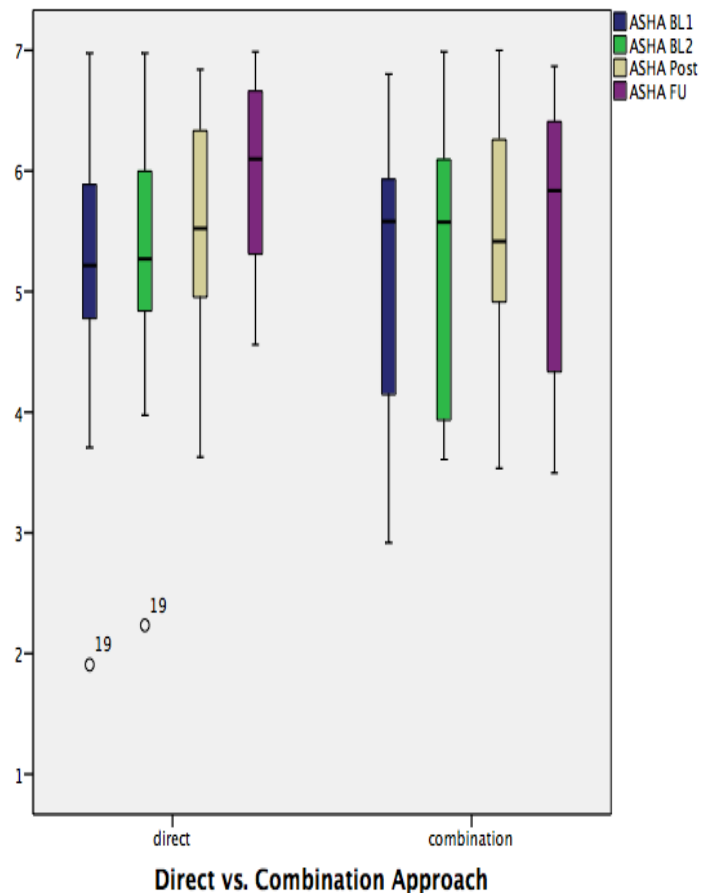
5.3.3.2.2.1 ASHA - FACS Direct versus Combination Approach

Figure 5.27 contrasts the ASHA -FACS measure functional communication scores of the direct versus the combination approach at the four assessment points. Detailed descriptive statistics can be found in Appendix I, 5.3.3.2.2.1.

Figure 5.27: Boxplots showing distribution of scores on ASHA -FACS measure for direct vs. combination approach

Median scores increased post-therapy and at follow-up for the direct group; for the combination group they only increased at follow-up. Mean scores remained relatively stable for both approaches between the two baselines [direct: BL1 mean (SD) = 5.21 (1.12), BL2 mean (SD) = 5.30 (1.08) and for combination: BL1 mean (SD) = 5.11 (1.13), BL2 mean (SD) = 5.15 (1.20)]. Scores slightly increased for both groups after therapy [direct: post

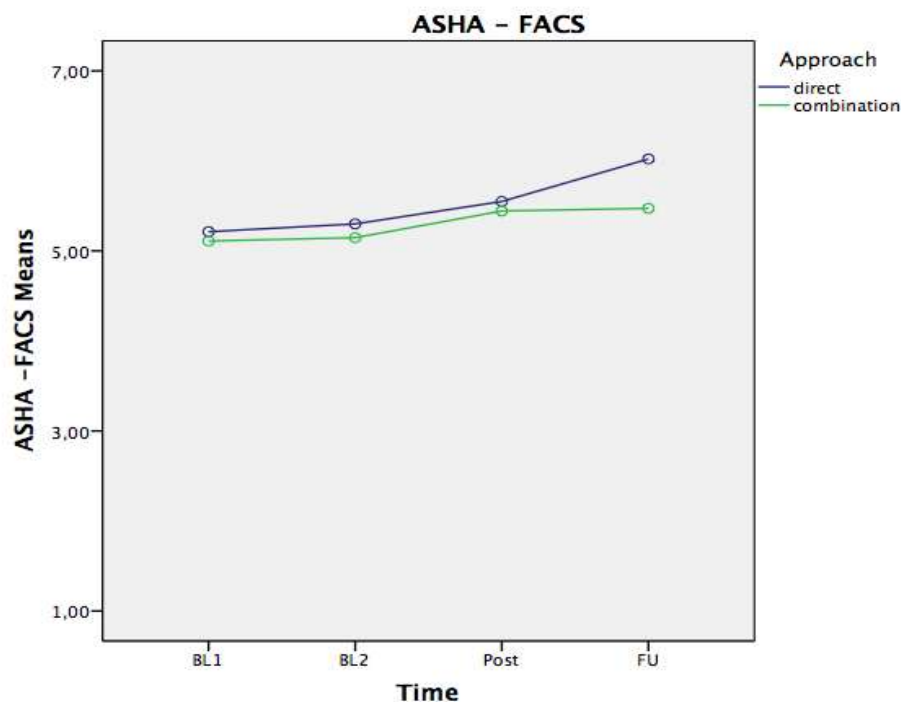
mean (SD) = 5.55 (.94) and combination: post mean (SD) = 5.44 (.97)]. At the follow – up evaluation there was a minimal increase between post –therapy assessment and follow up for the combination group [follow-up mean (SD) = 5.47 (1.18)] and a slight increase



for the direct approach group [follow-up mean (SD) = 6.02 (.73)]. There was one outlier at the baseline assessments of the direct approach group. Scores for both approaches across the four time points were near-normally distributed (skewness = -.11 – -1.01).

A two-way mixed ANOVA with two levels in the between factor (direct vs. combination) and four levels in the within factor (four assessments across time) was carried out to explore whether there was a significantly different pattern of change across time between the two groups. The effect of group was not significant $F(1, 34) = .55, p = .466$. There was a significant main effect of time, Greenhouse - Geisser $F(2.16, 73.26) = 7.26, p = .001$ with a large effect size ($\eta^2_p = .176$). In pairwise comparisons, the only significant differences were between the two baselines and the follow-up assessment (mean differences = .58 and .52, $p = .005$ and $p = .026$ respectively). The interaction effect was not significant Greenhouse - Geisser $F(2.16, 73.26) = 1.16, p = .322$ (Figure 5.28).

Figure 5.28: Mean scores of ASHA - FACS for direct vs. combination approach

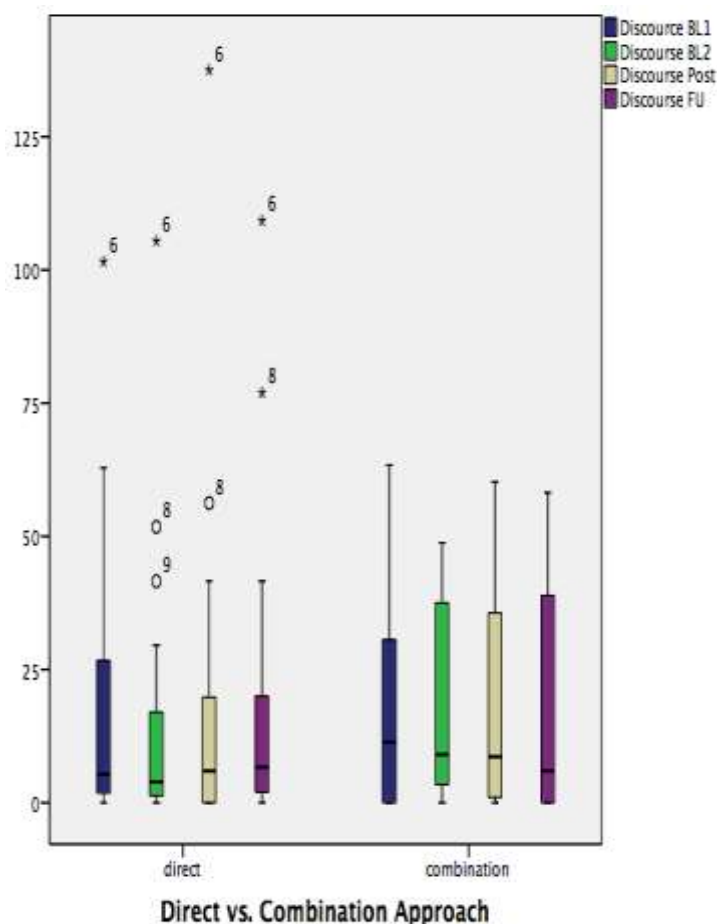


5.3.3.2.2.2 Discourse “Cookie Theft” Picture Direct versus Combination Approach

Figure 5.29 contrasts the discourse scores of the direct and combination approach at the four assessment points. Detailed descriptive statistics can be found in Appendix I, 5.3.3.2.2.2.

Figure 5.29: Discourse scores for direct vs. combination approach

Median scores appeared relatively stable across time for both therapy groups. Mean scores for both groups showed a small decrease from the first baseline to the second baseline [direct: BL1 mean (SD) = 16.18 (25.03), BL2 mean (SD) = 14.74 (24.73) and for combination: BL1 mean (SD) = 17.45 (21.87), BL2 mean (SD) = 16.63 (18.15)]. At the post therapy evaluation, a small increase was found for both approaches [direct: post mean (SD) = 17.43 (31.03)



and combination: post mean (SD) = 18.23 (21.48)]. Scores slightly decreased at the follow – up for the combination approach and slightly increased for the direct approach [direct: follow – up mean (SD) = 17.93 (27.80) and combination follow – up mean (SD) = 17.13 (21.71)]. As the boxplot illustrated, at the direct approach group one participant was an outlier at BL2, one participant was an outlier at BL2 and post therapy and an

extreme outlier at follow-up, and one participant was an extreme outlier at all assessment points. Scores were highly skewed across time points for the direct group (skewness = 2.31 – 3.08) and skewed at BL1 and FU for the combination group (skewness = 1.2 – 1.06). Based on the boxplots, the small differences in means across time in the context of very high standard deviations and the non-parametric nature of the data, no mixed ANOVA was carried out.

5.3.3.2.3 Personal Factor Level Results

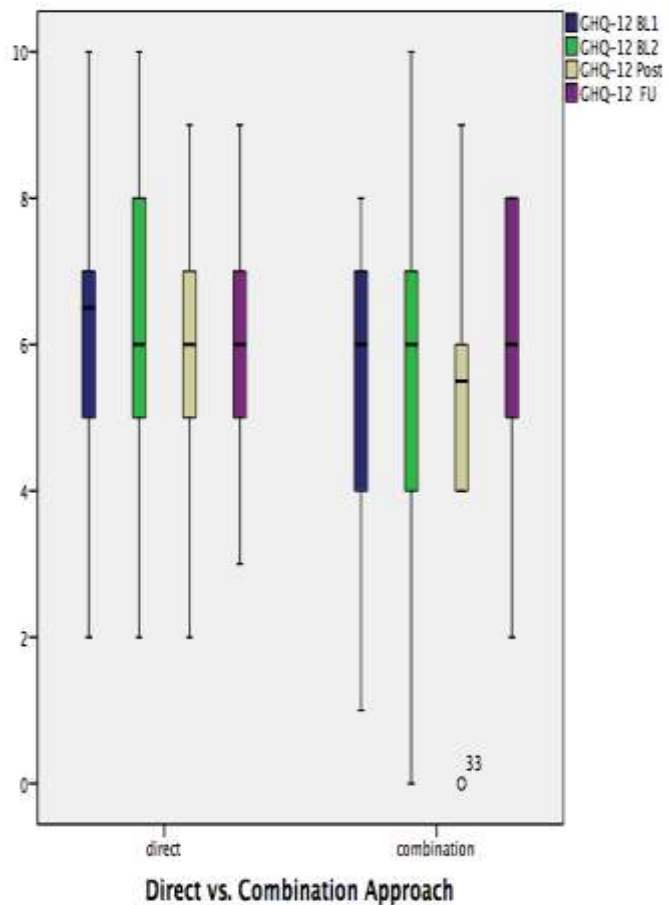
5.3.3.2.3.1 GHQ-12 Direct versus Combination Approach

Figure 5.30 contrasts the GHQ-12 scores of direct versus combination approach at the four assessment points. Detailed descriptive statistics can be found in Appendix I, 5.3.3.2.3.1.

Figure 5.30: GHQ-12 scores for direct vs. combination approach

Both medians and mean scores on the GHQ-12 remained between 5 and 6 across the time points: combination approach group BL1 mean (SD) = 5.50 (1.99), BL2 mean (SD) = 5.50 (2.50), post mean (SD) = 5.21 (2.19), follow – up mean (SD) = 6.00 (1.75), and direct approach group BL1 mean (SD) = 6.32 (1.91), BL2 mean (SD) = 5.91 (2.39), post mean (SD) = 6.00 (1.72), follow -up mean (SD) = 5.86 (1.67). As the boxplot illustrated, at the combination approach group one participant was an outlier at the post –

therapy assessment point. Scores for both groups across the four time points were normally distributed (skewness = -.003 - -.82). Based on the boxplots and the mean scores, no mixed ANOVA was carried out, as scores for both groups across time were similar.



5.3.3.2.4 Quality of Life Level Results

5.3.3.2.4.1 SAQOL- 39g Direct versus Combination Approach

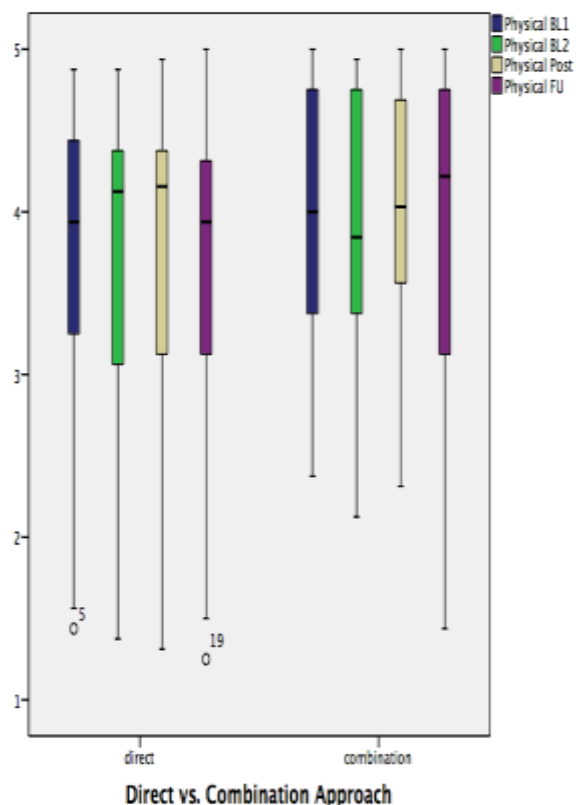
The SAQOL-39g has three domains - physical, psychosocial and communication - and an overall health related quality of life score.

I) Physical Domain

Figure 5.31 contrasts the physical domain scores of the direct versus the combination approach group at the four assessment points. Detailed descriptive statistics can be found in Appendix I, 5.3.3.2.4.1.I.

Figure 5.31: SAQOL-39g physical domain scores of the direct vs. combination approach

As expected for this domain, medians were relatively stable ending up at the same score at post-therapy as at BL1 for the direct approach and slightly higher for the combination approach. Similarly, mean scores remained relatively stable for both groups across all assessment points [direct: BL1 mean (SD) = 3.62 (1.05), BL2 mean (SD) = 3.64 (1.07), post mean (SD) = 3.82 (.91), follow - up mean (SD) = 3.66 (1.07), and combination: BL1 mean (SD) = 3.91 (.87), BL2 mean (SD) = 3.74 (.98), post mean (SD) = 3.98 (.85), follow - up mean (SD) = 3.86 (1.06). There was one outlier at the first baseline and another at the follow-up of the direct approach group.



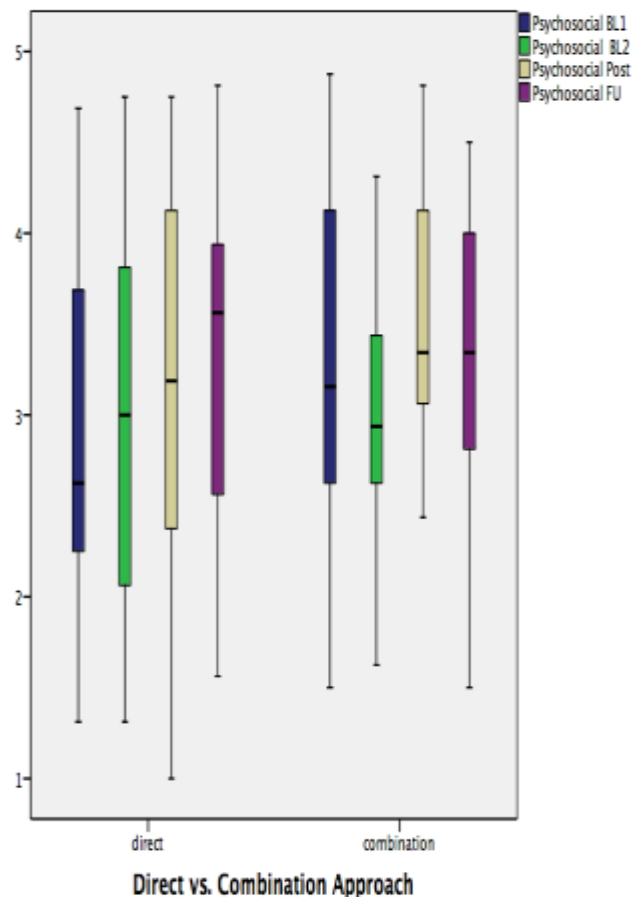
Scores were normally distributed with the exception of the direct approach at the post therapy evaluation (skewness = -1.25). No further statistical analysis was undertaken.

II) Psychosocial Domain

Figure 5.32 contrasts the psychosocial domain scores of the therapy group versus the control group at the three assessment points. Detailed descriptive statistics can be found in Appendix I, 5.3.3.2.4.1.II.

Figure 5.32: SAQOL- 39g psychosocial domain scores of the direct vs. combination approach

The median for the direct approach increased across time; for the combination approach it increased at post-therapy and then remained stable. Direct approach group mean scores followed a similar pattern: they increased by small steps across the assessment points [BL1 mean (SD) = 2.87 (1.02), BL2 mean (SD) = 2.91 (1.05), post mean (SD) = 3.08 (1.10), follow - up mean (SD)= 3.32 (.92)], whereas for the combination approach group the double baseline scores were similar but after therapy scores increased a

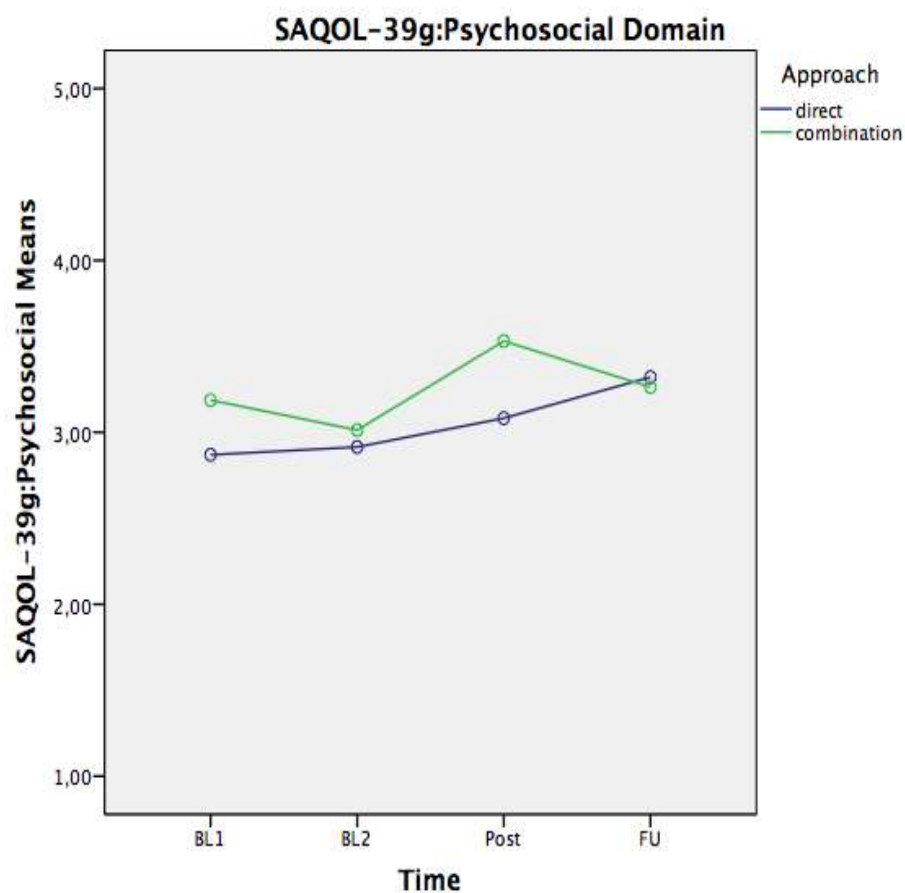


bit and decreased again at the follow -up evaluation [BL1 mean (SD) = 3.18 (.94), BL2 mean (SD) = 3.01 (.73), post mean (SD) = 3.53 (.70), follow - up mean (SD)= 3.26 (.83)].

Scores for both approaches across the four time points were normally distributed (skewness = -.55 – .26).

A two-way mixed ANOVA with two levels in the between factor (direct vs. combination) and four levels in the within factor (four assessments across time) was carried out to explore whether there was a significantly different pattern of change across time between the two groups. The effect of group was not significant $F(1,34) = .62, p = .44$. The main effect of time was not significant, $F(2.25, 76.36) = 2.41, p = .090$, though the effect size was large ($\eta^2_p = .50$). There were no significant differences in pairwise comparisons. The interaction effect was not significant, $F(2.25, 76.36) = .98, p = .39$ (Figure 5.33).

Figure 5.33: Mean scores of SAQOL- 39g psychosocial domain of the direct vs. combination approach

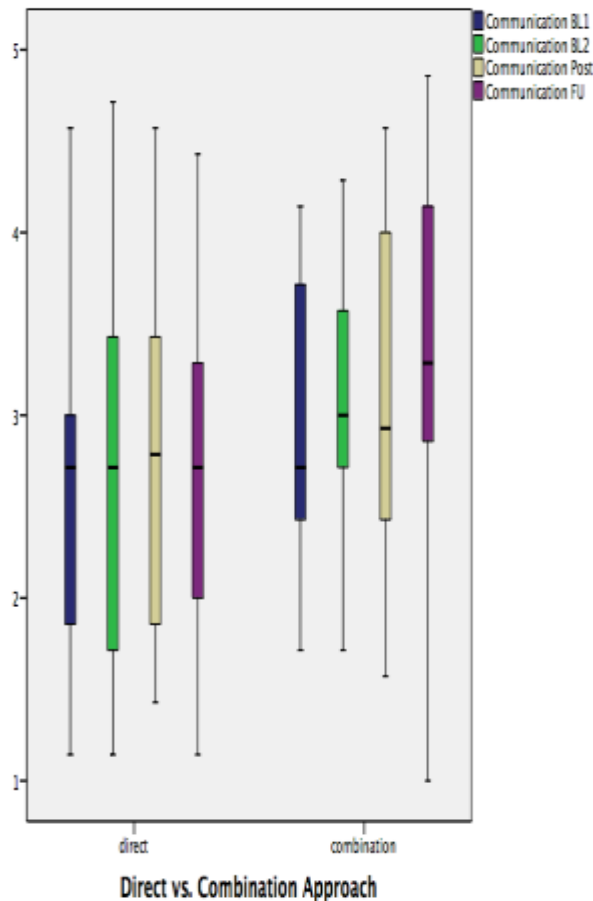


III) Communication Domain

Figure 5.34 contrasts the communication domain scores of the direct versus combination approach group at the four assessment points. Detailed descriptive statistics can be found in Appendix I, 5.3.3.2.4.1.III.

Figure 5.34: SAQOL-39g communication domain scores of the direct vs. combination approach

The median for the direct approach was stable across baselines, increased post therapy, but then dropped to pre-therapy levels. The median for the combination approach increased from BL1 to BL2 and then again at follow up. Both approaches mean scores showed an increase across all assessment points [direct: BL1 mean (SD) = 2.60 (.90), BL2 mean (SD) = 2.68 (.98), post mean (SD) = 2.71 (.97), follow - up mean (SD) = 2.78 (.95) and



combination: BL1 mean (SD) = 2.92 (.79), BL2 mean (SD) = 3.03 (.76), post mean (SD) = 3.12 (.94), follow - up mean (SD)=3.26 (1.15)]. Scores for both groups across the four time points were normally distributed (skewness = -.65 – .53). As the mean scores across time did not suggest a different pattern of change between the two groups across time, no further statistical analysis was undertaken.

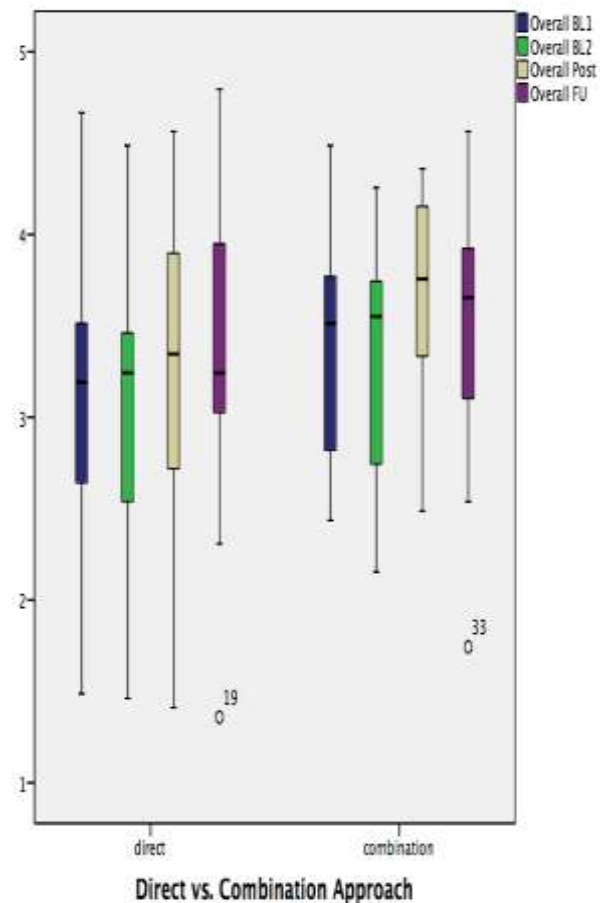
IV) Overall SAQOL-39 score

Figure 5.35 contrasts the overall domain scores of the direct versus combination approach group at the four assessment points. Detailed descriptive statistics can be found in Appendix I, 5.3.3.2.4.1. IV.

Figure 5.35: SAQOL-39g overall domain scores of the direct vs. combination approach

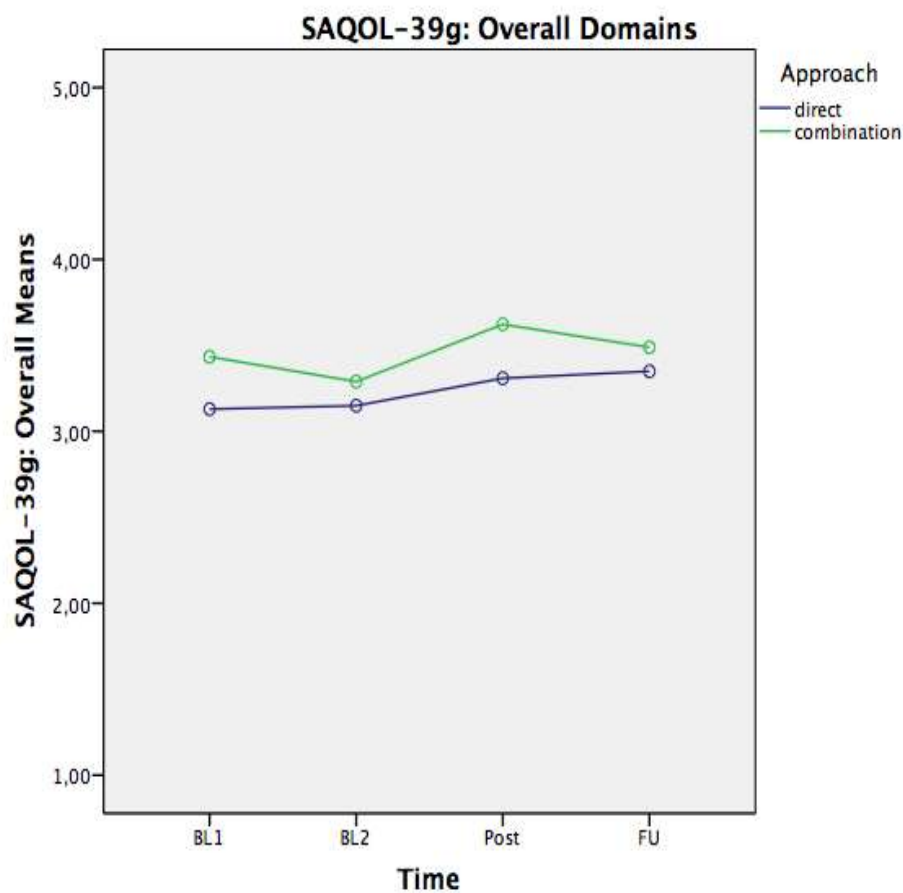
Medians for the direct approach ranged by 0.16; for the combination approach the median increased 0.21-0.25 post-therapy and then dropped by 0.11. Direct approach group mean scores were stable across baselines and increased at post-therapy and follow up [BL1 mean (SD)= 3.13 (.75), BL2 mean (SD) = 3.15 (.79), post mean (SD) = 3.31 (.78), follow - up mean (SD)= 3.35 (.78)]. Combination approach group scores decreased from BL1 to BL2, they increased after therapy and decreased again at the follow-up evaluation [BL1 mean (SD)= 3.43 (.60), BL2 mean (SD) = 3.28 (.61),

post mean (SD)=3.62 (.57), follow - up mean (SD)= 3.49 (.73)]. An outlier at the follow - up assessment point was found for both approaches. Scores for both groups across the four time points were normally distributed with the exception of the follow-up assessment for the combination approach group (skewness = -1.04).



A two-way mixed ANOVA with two levels in the between factor (direct vs. combination) and four levels in the within factor (four assessments across time) was carried out to explore whether there was a significantly different pattern of change across time between the two groups. The effect of group was not significant $F(1,34) = 1.04$, $p = .315$. The main effect of time was significant, $F(2.06, 70.17) = 3.18$, $p = .046$, with a medium effect size ($\eta^2_p = .09$). There were no significant differences in pairwise comparisons. The interaction effect was not significant, $F(2.06, 70.17) = .57$, $p = .572$ (Figure 5.36).

Figure 5.36: Mean scores of SAQOL- 39g overall domain of the direct vs. combination approach



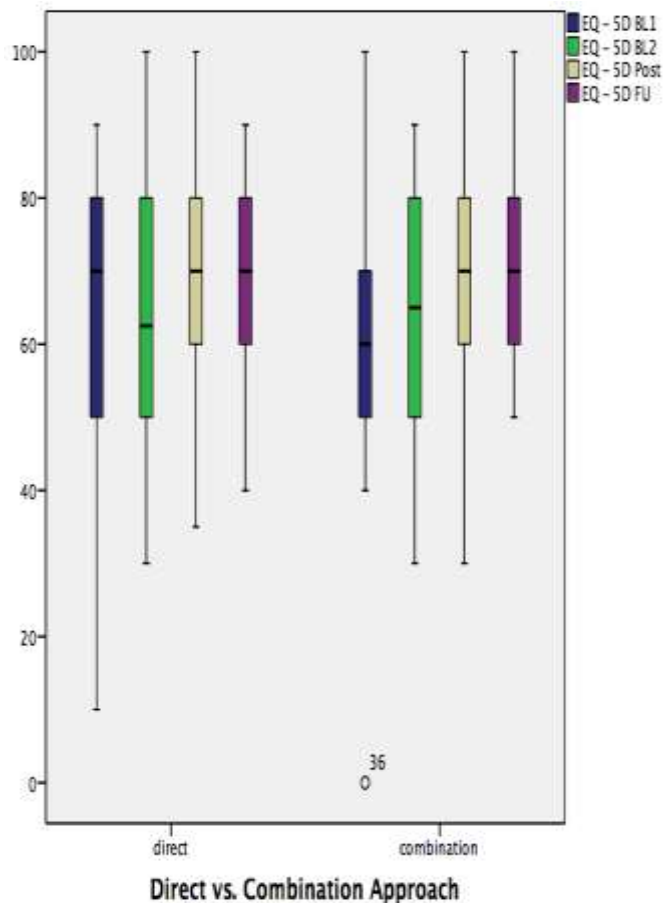
5.3.3.2.4.2 EQ-5D Direct versus Combination Approach

Figure 5.37 contrasts the EQ-5D visual analogue scale (VAS) scores of the direct versus combination approach group at the four assessment points. Detailed descriptive statistics can be found in Appendix I, 5.3.3.2.4.2.

Figure 5.37: EQ-5D visual analogue scale (VAS) scores of the direct vs. combination approach

Median scores ranged 62.50 – 70 for the direct approach and 60-70 for the combination approach. Mean scores of the direct approach group were stable across the double baseline [BL1 mean (SD)= 63.73 (18.37), BL2 mean (SD)= 63.41 (18.86), whereas the scores of the combination approach group increased from BL1 to BL2 [BL1 mean (SD) = 59.29 (25.26), BL2 mean (SD) = 63.57 (19.46)]. Scores increased by 3.73 points (0-100 scale) from the BL2 to post – therapy for the direct approach group and

remained stable at follow –up [post mean (SD) = 67.14 (17.06), follow - up mean (SD) = 66.82 (13.23). Scores of the combination approach group increased from BL2 to post-therapy, by 4.64 points, and from post-therapy to follow –up, by 2.5 points [post mean (SD) = 68.21 (17.05), follow - up mean (SD) = 70.71 (14.53)]. There was one outlier at



the first baseline assessment of the combination approach group. Scores were normally distributed with the exception of the first baseline assessment for the direct approach group (skewness = -1.26). Given the visual inspection of the data and the small differences in mean scores in the context of much larger standard deviations, no further statistical analysis was undertaken.

5.3.4 Summary of comparisons between the two therapy approaches (direct versus combination) and adjusting for multiple comparisons

Five mixed ANOVAs were carried out to compare outcomes between the direct approach group (n= 22) and the combination approach group (n = 14). Five measures (Discourse analysis, GHQ-12, Physical and Communication domain of SAQOL-39g, EQ 5D) were not analysed with mixed ANOVAs. Adjusting for the originally planned comparisons (10) with a Bonferroni correction ($0.05 / 10 = .005$), the following differences remained significant: There was a significant main effect of time ($p < .001$) for the main outcome measure of naming the Snodgrass and Vanderwart pictures, with a small but significant difference between BL1 and BL2 (mean difference = 10.23, $p = .003$), large significant differences between BL1 to post-therapy and BL1 to follow up (mean differences = 49.69 and 43.46, $ps < .001$), and large significant differences between BL2 to post – therapy and follow – up (mean differences= 39.46 and 33.22, $ps < .001$). There was also a significant main effect of time for the BNT ($p < .001$), with a significant difference between BL1 to post-therapy and follow-up (mean differences = 4.73 and 3.54, $p < .001$ and $p = .003$ respectively) and a significant difference between BL2 and post-therapy (mean difference = 4.25, $p = .001$). Lastly, there was a significant main effect of time for the ASHA-FACS ($p = .001$), with a significant difference between BL1 to the follow -up assessment point (mean differences = .58, $p = .005$). The main effect of time for the overall SAQOL-39g ($p = .046$) with the medium effect size was no longer significant after the Bonferroni correction.

Interestingly, no interaction effects were significant. That is, there were no significant differences between the direct and the combination approach groups in their pattern of change across time on any of the outcome measures.

Chapter 6: Discussion

6.1 The current study in the context of the evidence base

Two theoretical approaches to aphasia therapy have emerged in the last few decades: one approach focuses on restoring language whilst the other focuses on the consequences of that impairment (Worrall, 2006). Aphasia therapy can be impairment-based or functionally oriented (Galletta, 2014). Each approach targets different domains in the ICF framework. Impairment – based therapy targets the body functions and structures domain of the ICF and the focus of the intervention is on areas such as word finding, grammar. Functionally oriented therapy focuses on the activity and participation domains of ICF. The activity domain considers life activities in which an individual engages and how a health condition affects an individual's activities. Examples of activities that may be affected secondary to aphasia are talking on the telephone, asking for directions to a location, or sharing a story. The participation domain includes an individual's participation in society and the effects of aphasia on social roles and life situations such as attending church or a social event. Each approach has evidence of effectiveness in improving difficulties of people with aphasia (Brady, Kell, Godwin, Enderby & Campbell, 2016). Nowadays, more and more studies investigate whether both therapy approaches can affect not just the targeted but also other domains of the ICF. This thesis has applied an impairment – based therapy protocol. However, secondary outcomes were also selected to explore potential changes after treatment in activity, participation and personal factor domains of the ICF, as well as quality of life.

This study takes a modified version of an established therapy, elaborated Semantic Feature Analysis (ESFA) and explores whether gains elicited by an impairment based protocol, like ESFA, manifest in other domains of the WHO ICF framework. This is an important, novel aspect of the current study as, to the best of our knowledge, it is the first study of SFA that has investigated not only gains in the domain of impairment, but also perceived changes to an individual's activity/ participation, well-being and

quality of life. Results were positive for the main outcome measure but varied across the secondary outcome measures.

A growing body of research has examined the effectiveness of SFA therapy mainly with moderate to mild aphasia severity participants. Systematic reviews of studies have reported that SFA is an effective therapy to treat naming deficits (Boyle, 2010; Maddy et al., 2014; Efstratiadou, under review). As systematically reviewed in a previous chapter (see Chapter 2) and reported by Maddy et al. (2014), therapy studies of SFA employed single case and case series designs. The current research, on the other hand, is the first known randomised control study of SFA. This study provides a higher level of evidence for SFA therapy, as the design employs a control / delayed therapy group, therefore it allows a greater confidence in the results on the efficacy of the treatment. In addition, it is the first study to test SFA therapy delivered in different therapy approaches (direct versus combination), utilizing the same intensity and dosage of therapy to allow comparisons over therapy approach to be made.

The overall aim of the thesis is to determine the efficacy of ESFA as a therapy method for treating naming deficits, and to explore whether it leads to secondary gains on the different domains of WHO ICF framework, including quality of life. This chapter will: i) summarize the key findings of the study, ii) relate these findings to the current literature, interpret and discuss them, iii) identify the relative strengths and limitations of the study, iv) discuss the clinical implications of the study and v) make recommendations for future research.

6.2 Efficacy of ESFA Therapy versus Control / Delayed Therapy

The first aim of the research was to examine the efficacy of ESFA therapy by comparing a therapy versus a controlled/ delayed therapy group.

6.2.1 Primary Outcome Measure: Snodgrass and Vanderwart Naming Test Therapy versus Controlled / Delayed Therapy Group

A significant overall improvement on the primary outcome measure of naming pictures of Snodgrass and Vanderwart was reported after therapy, for the therapy group. A different pattern of change was evident for the two groups. The controlled/ delayed therapy group showed a small increase of scores (within 15 points) across the three assessment points, whereas the therapy group scores remained similar at the two baseline assessments, but increased by more than 40 points from the highest baseline point to post-therapy.

These findings contribute to the literature (Boyle, 2010; Maddy et al., 2014; Efstratiadou, under review) and suggest that a modified type of SFA, the ESFA therapy, is an effective intervention for improving confrontational naming. The positive therapy gains of the current control study are in line with the findings of single case/case series studies in the literature that used the same type of primary outcome measure – a confrontation naming task of nouns (Massaro & Tompkins, 1994; Boyle & Coelho, 1995; Coelho et al., 2000; Boyle, 2004; Davis & Stanton, 2005; Hashimoto & Frome, 2011; Hashimoto, 2012; van Hees et al., 2013; Kristensson et al., 2015; DeLong et al., 2015; Mehta & Isaki, 2016).

A strength of this study was the inclusion of people with severe aphasia. In our recent review of the literature of SFA therapy studies (Efstratiadou et al., under review), the only study that included a participant with global aphasia was DeLong and colleagues' (2015). In the present study, 10 individuals had global aphasia and of these, seven were randomised in the therapy group. In DeLong and colleagues' study no positive change on trained items was reported. In this study, all individuals, except for one, showed

improvements in naming immediately after the end of therapy. The positive findings in the present study may relate to following a condition of few - exemplars, like in studies of Coelho et al. (2000) and in Boyle (2004). Few - exemplars condition means that the same small number of treatment pictures is used in each treatment session. In our study, we started with few target pictures (2 to 3 pictures for individuals with global aphasia) and we added new, only when the individual had named them correctly for three consecutive sessions and there was time left in the session. So, the number of trained words for each participant varied, but was kept small ($n = 8 - 19$) for all individuals with global aphasia. On the other hand, DeLong et al. (2015) used three sets of pictures of different semantic categories for each participant, set 1 (birds and furniture) and 2 (zoo animals and clothing) contained 32 items each and set 3 (insects and musical instruments) contained eight items. Treatment was sequentially applied to sets 1 and 2. These sets were further divided into four subsets of eight items – treatment items, and three sets of untreated items controlled for semantic relatedness, exposure in naming/probing and knowledge of phonological form. In each treatment session, the SFA protocol was completed with the eight items designated for treatment, and was followed by naming exposure with eight untreated items. It may be that the therapy process in DeLong study (2015) followed a complicated structure, which was not helpful for individuals with global aphasia. It may also be that our treatment led to higher exposure rates to the few treated items, which was needed for providing positive changes on naming accuracy.

The underlying mechanism of how improvements in naming accuracy are achieved in ESFA are similar to those of SFA. Like SFA, ESFA is based on the notion of spreading activation within the semantic system (Collins & Loftus, 1975). Especially, the semantic processing level is conceptualized as a network of semantic representations and links that are interconnected to other related representations. The presentation of features that are strongly related to the targeted picture results in spreading of activation that converges onto the target concept, which receives a higher level of activation compared to other similar concepts. This targeted concept then activates the phonological information associated with it and this leads to the oral production of the target word. An important difference between ESFA and SFA is that ESFA uses the elicited features for

creating a sentence. This will be examined further at the evaluation of the secondary outcome measures and particularly outcomes of the discourse measure.

As far as baseline assessments are concerned, in our study there was a small but significant change, over the pre-therapy phase (between BL1 and BL2). The improvement is unlikely to be due to spontaneous language recovery, which mostly occurs in the first 3 or 4 months post-stroke (Holland & Greenhouse, 1989; Laska, Hellblom, Murray, Kahan & Von Arbin, 2001) and participants in our study were four to 207 months post-stroke. One possible explanation could be the regular contact and language-related activities that participants had during this time with neurolinguistics and neuropsychology researchers collecting data for the broader Thales aphasia project. Another explanation could be familiarity with the assessment task. Familiarity describes how frequently something is encountered or a word is seen (Dorry, 2010). In the pre-therapy phase of our study, in a period of six weeks, participants were exposed four times to the same assessment task (oral confrontation-naming task of all 260 pictures): once at the baseline 1 and three times at baseline 2 in order to select the items to be treated with each individual. Familiarity can have a positive influence on word retrieval therapy in chronic aphasia (Davis, 2007; Goodglass, 1993), regardless of patient severity of impairment. One could then argue that a familiarity effect could undermine the treatment effect of the study. To test this hypothesis an analysis of the named items of each participant would have to be undertaken, as in Dorry (2010), to report the percentage of familiar and unfamiliar items named post therapy for each individual. Dorry (2010) examined the effect of familiarity on word retrieval therapy with four native English-speaking individuals with chronic aphasia. Phonological Components Analysis (PCA) and SFA treatments were tested in a crossover design. Therapy focused on retrieval of familiar and unfamiliar words based on participant self – rating. Findings showed improvement for familiar treated stimuli for all participants. Type of treatment (phonological or semantic) did not appear to influence findings. It is therefore possible that in our study the small baseline improvement observed was due to the frequency of encountering the same words in the confrontation – naming task.

6.2.2 Secondary Outcome Measures for the Therapy versus Control / Delayed Therapy Group

6.2.2.1 Body Functions and Structure - Impairment - Based Level Results

6.2.2.1.1 BNT for the Therapy versus Control / Delayed Therapy Group

It was hypothesized, based on suggestions by Kiran and Bassetto (2008) that improvement in naming treatment would likely be accompanied by improvements on a standardized measure of naming such as the BNT. They argued that improvements in therapy may be accompanied by improvements on language tasks that are similar to those targeted in therapy and therefore rely on similar processing mechanisms. This was not the case in this study. There was a significant main effect of time and pairwise comparisons showed there was a significant difference between BL1 and post-therapy/BL3 and BL2 and post-therapy/BL3, and not a significant difference between the two baseline assessments. Although, visual inspection of the data, suggested the same pattern of change as in the primary outcome, with a sharper increase in scores for the therapy group from second baseline to post therapy, the interaction effect was not significant. There was a trend for the therapy group to improve more on their naming accuracy but the effect was not large enough to be picked up as a significant finding.

These findings suggested an item-specific improvement post therapy, with treated items (as those included in the primary outcome measure) improving and untreated items (BNT) not improving statistically. This may indicate that although, the treatment was effective, there was no generalisation to untreated items. Or it may be that the generalisation effect was too small to be picked by the power of this study.

The generalisation findings of SFA studies, which have used the BNT as an outcome measure, are mixed. Some individuals showed a significant improvement in their scores on the BNT, like participants KJ in Hashimoto's study (2012) (28/60 pre-therapy, 43/60 post therapy) and P2 in Rider et al.'s (2008) study (29/60 pre-therapy, 36/60 post therapy). Others showed minimal or no increase, like P2 in Antonucci (2009) (7/60 pre and post therapy), or MB in Hashimoto and Frome (2011) (12/60 pre therapy, 13/60 post therapy).

Significant improvement on the BNT measure would provide evidence that ESFA therapy can have a generalisation effect. Boyle (2004) stated generalisation to untreated words might occur in at least two different ways based on the theoretical mechanisms of SFA. She suggested that words from the semantic categories that were accessed during therapy might benefit more, as a result of repeated stimulation of those categories. On the other hand, maybe treated word categories are not so important but rather the repeated stimulation of the semantic system in a methodical way might make access to the system easier in general. Boyle in her study of 2004 conducted a post hoc analysis for determining which of these two ways leads to positive changes to untrained items. She found that generalisation occurred from the repeated methodical accessing of the semantic system, regardless of semantic category. If this is the case, then one could expect the BNT, which may or may not include words from the same categories as those treated for each participant, to improve in our study due to the methodical stimulation of the semantic system.

In summary, in this study there was no significant generalisation effect on the BNT scores. BNT scores showed a trend of greater improvement for the therapy group, but this trend was not large enough to be picked up as a significant change, with this study's sample size. Studies with larger samples of participants would help demonstrate with more confidence whether gains from ESFA therapy generalise to untreated items.

6.2.2.2 Activity and Participation Level Results

6.2.2.2.1 ASHA - FACS for the Therapy versus Control / Delayed Therapy Group

Functional communication of participants, in terms of activities performed, was evaluated with the ASHA – FACS. ASHA – FACS was chosen as it is rated by a significant other, thus reducing respondent burden. Furthermore, as ASHA - FACS asks about communicative activities that people with aphasia perform and whether they perform them independently or with assistance, it provides information from the perspectives of a significant other on the communication skills of the person with aphasia. From this assessment tool, we can obtain functional communication information for many real-life communication situations, such as requesting information from others, explaining how to do something, expressing feelings, writing a message and following directions.

In the current study, ASHA – FACS did not show a substantial change or a different pattern of change in participants' functional communication between the two groups. Data were not analyzed with mixed ANOVA, due to the small differences in means across time and the non-parametric nature of the data: scores for the control / delayed therapy group showed a small numerical increase across the three assessments, whereas scores for the therapy group were similar between the two baselines but increased by .31 (out of seven) points from the highest baseline to the post therapy evaluation. The increase was minimal and no change across time and no interaction effect could be suspected.

Results of ASHA – FACS suggest that despite the significant improvement of the therapy group's confrontation naming skills, their significant others did not perceive a change in their functional communication skills. This outcome could be due to ESFA, as an impairment – based therapy not targeting communication, but only naming improvement. Though participants in this study went beyond the single word level to producing phrases and sentences, their utterances did not have communicative intent. It maybe that a therapy that specifically requires the use of single words acquired in therapy

in communication activities would be more likely to lead to positive changes in individuals' functional communication skills.

Only a small number of SFA studies, have used an activity domain measure in their outcome measurement. Boyle and Coelho (1995) used the Communicative Effectiveness Index (CETI; Lomas et al., 1989) to determine if SFA treatment had an impact on participant communication effectiveness outside of treatment. CETI was completed by HW's daughter before treatment and during the final probe session. HW received a pre-treatment score of 65.56 and a post-treatment score of 77.56, yielding a change score of 12.00. This represents a clinically important improvement (Lomas et al., 1989). Davis and Stanton (2005) used the ASHA – FACS, completed by the participant's spouse at the beginning and end of therapy to assess functional communication skills in the home setting. Post – therapy improvements were noted in most areas of social communication on the ASHA FACS, as J.S. progressed from requiring at least moderate assistance (score of 5) in six out of 28 areas to requiring moderate assistance in only one area (explaining how to do something). Kristensson and colleagues (2015) measured generalisation to functional communication as perceived by the participants and their significant others. The Communication Outcome After Stroke (COAST) scale (Long, Hesketh, Paszek, Booth, & Bowen, 2008) and the carer COAST scale (Long, Hesketh, & Bowen, 2009) were used. Both scales were administered by two speech and language therapy students, not otherwise associated with the study, in the participants' homes on three occasions: before therapy, immediately after therapy, and 10–12 weeks after the end of therapy. The COAST scale enables participants to rate their self-perceived functional communication skills and the impact of functional communication on their everyday quality of life. Although, no improvement in the participants' confrontation-naming ability was reported, two of the three participants rated their functional communication skills higher at follow – up than before therapy. Kristensson suggested such results could imply that the intervention was so demanding that participants found it hard to appreciate any positive changes immediately post therapy and also perhaps positive changes were not apparent until the participant had some time to implement the improved communicative skills in everyday life. Regarding the ratings of the carers at follow up,

they reported one slight decrease, one slight increase and one considerable increase. Though the findings of this study cannot be directly compared to ours, it is interesting that in the Kristensson study there was no improvement in confrontation naming. Mehta and Isaki (2016) asked each participant's spouse to complete the CETI before and after treatment to determine if their modified SFA treatment had an impact on the participants' communication effectiveness. The pre- and post-treatment CETI scores for both participants of the study indicated that the spouses observed functional changes in the participants' everyday communication effectiveness outside of treatment. In summary, unlike our study, the studies discussed here report that carers / significant others of people with aphasia report communication effectiveness gains following SFA. Yet, none of these studies included a control condition (multiple baseline) or control group, in contrast to our study. Carer / significant other views may be affected by the fact that their loved one is receiving intervention. Without a control condition, it is impossible to unravel whether it is the specific intervention rather than the general contact the PWA receives that makes this difference in the carer / significant other views. Therefore, these studies and ours provide no strong evidence of gains in functional communication following SFA treatment.

6.2.2.2.2 Discourse “Cookie Theft” Picture for the Therapy versus Control / Delayed Therapy Group

Performance on the “Cookie Theft” picture of BDAE was assessed to provide a measure of discourse skills. Some studies have associated SFA therapy of nouns with positive changes in discourse (Boyle, 2004); and SFA therapy of verbs with substantial increase in word naming, increase of correct information units (CIUs) and per cent CIUs per minute (Wambaugh & Ferguson, 2007). Though other studies which tested SFA in discourse have not reported positive changes (Rider et al., 2008), it was hypothesized that the current procedure could have an impact on discourse. This hypothesis was based on our use of ESFA, which encourages the use of generated semantic features in phrases (Papathanasiou & Mihou, 2006). This hypothesis was not supported by the findings of this study. While treated individuals improved their confrontation naming, a similar

change was not demonstrated on the “Cookie Theft” picture. Only a small, non-significant improvement was found for the therapy group immediately after therapy, with no change across the three assessment points for the control/ delayed therapy group.

The present study tested performance on discourse level, immediately after therapy ended, as it wanted to find out whether improvement in naming, and phrase production with the features of the target word would cause a change in discourse. Literature suggests that outcomes could be more favourable when discourse tasks are trained during therapy sessions, as in the studies of Peach and Reuter (2010), Antonucci (2009) and Falconer and Antonucci (2012). Peach and Reuter (2010) used picture descriptions and procedural questions, Antonucci and Falconer (2009) and Antonucci (2012) trained discourse in a group setting. These studies suggest that if in our study we had included training tasks that were more similar to natural communication contexts, then it would have been more plausible to expect discourse level changes.

An issue in the present study, and in all single word production studies, like SFA or even single phrase production, like ESFA, is that they use single pictures during therapy to elicit single words or short phrases, while they also use a single picture, though more complex to elicit a longer discourse. This similarity in elicitation stimuli may have prompted participants to produce short outputs when a discourse was really aimed for. Moreover, the Snodgrass and Vanderwart pictures used in this study include words from animals, objects or fruits, which are not applicable in the discourse assessment with the “Cookie Theft” picture. This lack of relationship between trained items and the “Cookie Theft” picture vocabulary may have contributed negatively to the results. A discourse measure more tightly related to the vocabulary trained during therapy would have been more likely to pick up a change. Yet, in this study we aimed to use independent secondary outcome measures, which can provide more convincing evidence of efficacy.

6.2.2.3 Personal Factor Level Results

6.2.2.3.1 GHQ-12 for the Therapy versus Control / Delayed Therapy Group

The emotional distress of people with aphasia in this study was evaluated with the GHQ-12 measure. GHQ-12 scores remained stable across time for both the control and the therapy group in our study (~6/12). There is limited evidence that naming therapy can lead to emotional gains for people with aphasia. In a study by Best, Greenwood, Grassly & Hickin (2008), of the seven participants who completed a course of word finding therapy, four showed a change in a positive direction with respect to ‘emotional consequences’, one was stable, and two gave less positive views. In our study, distress scores were not affected by the therapy procedure, as the therapy group reported the same scores immediately after treatment. There were important differences between our treatment and the treatment in Best et al. (2008). They used phonological and orthographic cues in their therapy rather than semantic cues though this does not seem likely to have affected emotional consequences. A more important difference is that they included two phases in therapy, where in the second phase, therapy focused on using treated words in connected speech and conversation. Lastly, in the treatment, they included words chosen by the participants as personally and functionally relevant to them. Either or both of these factors may have facilitated changes in emotional wellbeing. Yet, none of these factors were used in our study, which relied on semantic cueing, naming items not self-selected and elaborating semantic features in phrases. Perhaps both using personally relevant items and practicing them in conversation may be important if changes in emotional aspects are to be expected with naming therapy.

A finding worth commenting on was that both groups experienced high distress levels. This finding is in line with studies of people with aphasia, where the prevalence of emotional distress and depression is high: 70% three months’ post onset and 62% one-year post onset (Kauhanen, Korpelainen, Hiltunen, Maatta, Mononen & Brusin et al., 2000). Thus, our findings add to the literature on the persistence of emotional distress and depression in people with aphasia; and they highlight the need for interventions to address this.

6.2.2.4 Quality of Life Level Results

6.2.2.4.1 SAQOL-39g for the Therapy versus Control / Delayed Therapy Group

The SAQOL-39g consist from three sub-domains, physical, communication and psychosocial and gives sub-domain and an overall score. Not all domains showed an improvement and different patterns of change across time were evident. Each domain is discussed separately.

Physical sub-domain outcomes were as expected, as speech and language therapy cannot lead to physical benefits. Scores remained similar across time and there was no difference between the groups. For the communication sub-domain, it was hypothesized that change in word retrieval could lead to changes in perceived communication, like in Best et al. (2008). In this study, scores of both groups showed minimal change across assessment points. Results are consistent with the other communication measures in this study: the ASHA-FACS and the “Cookie Theft” measure. So, it may be that ESFA does not lead to improvements in communication. Another possible explanation is that the communication domain of the SAQOL-39g is not sensitive enough to pick up potential changes in communication, as it consists of only 7 items. In contrast, the COAST scale used by Kristensson and colleagues (2015), which reported an effect in communication for one of the three participants immediately after therapy and a positive effect for 2 of the participants at the follow-up evaluation, consists of 20 items. Moreover, of these 7 items, 5 are testing functional communication skills and only 2 are testing the impact of functional communication on participants’ everyday quality of life.

The psychosocial sub-domain was the only sub-domain of the SAQOL-39g where a significant interaction effect was evident. Though after adjusting for multiple comparisons this effect was no longer significant ($p = .013$) the effect size was medium to large ($\eta^2p = .12$) suggesting an important difference. Findings showed that the therapy group improved post therapy, whereas the control group slightly deteriorated between the second and third evaluation. Though the improvement for the therapy group was small, it was consistent and the effect size was medium. It is interesting, in the current study, that the psychosocial domain of the SAQOL -39g picked up a therapy effect in contrast

to the GHQ measure. A possible explanation about this difference could be that, the GHQ is a measure of distress and emotions, whereas the psychosocial sub-domain of the SAQOL-39g includes aspects of emotional and social well-being. It may be that ESFA had more of an effect on social aspects of well –being.

Regarding, the overall scores of SAQOL-39g there was an important difference on the quality of life of the two groups of participants in this study ($p = .015$, $\eta^2_p = .11$). A different pattern of change was reported for the two groups, as scores for the therapy group improved from BL2 to post – therapy and scores for the control /delayed therapy group slightly deteriorated. This significant change on the overall score is likely driven by the significant outcomes of the psychosocial sub-domain (11 of the total 39 items from the 39).

These results on the psychosocial sub-domain and the overall SAQOL-39g score need to be interpreted with caution as the differences in scores are small. Yet, there is emerging evidence that even small changes on the SAQOL-39g are important for participants. A study in Singapore with 78 people with aphasia, estimated what the minimally important difference is for the SAQOL-39g (Guo, 2016). Minimally important difference (MID) is the smallest difference in a score that is perceived as important by respondents and which might influence management (Schünemann & Guyatt, 2005). In the Guo study, the MID for improvement in the SAQOL-39g was 0.21. In our study, the therapy group exceeded this MID and improved by 0.40-0.55 in the psychosocial domain and 0.21-0.28 in the overall score.

Our results seem to suggest that an impairment-based intervention, ESFA, can lead to positive changes in aspects of quality of life. These findings are consistent with existing literature on what factors affect quality of life. Cruice et al. (2003) and Hilari et al. (2003) have both suggested an important link between language, communication and quality of life in people with chronic aphasia. They found that both functional communication and language impairment predicted quality of life in their participants with aphasia. Further, in a review of studies on predictors of quality of life in people with aphasia, Hilari et al. (2012) confirmed that extent of the language impairment predicted

quality of life. It is therefore possible that reducing the underlying impairment - naming deficit in this study - can lead to an improvement in perceived quality of life.

This study is among the first control studies exploring the impact of a speech and language intervention on quality of life. The strongest evidence in this area comes from a recently published German randomised control trial of 158 participants with aphasia, which reported gains on the SAQOL-39 following intensive speech and language therapy (Breiteinstein, Grewe, Flöel, Ziegler, Springer et. al., 2016). There are important differences between this study and ours. The German study tested an intensive intervention (≥ 10 h per week), delivered for three weeks versus a deferred therapy group; and the intervention comprised both linguistic-cognitive and communicative-pragmatic approaches. As this body of literature emerges, it will help us understand better what intervention components are important to lead to quality of life gains for people with aphasia.

6.2.2.4.2 EQ-5D for the Therapy versus Control / Delayed Therapy Group

The EQ-5D was used to collect information for the economic evaluation of the intervention. The EQ visual analogue scale (VAS) was reported in the results as a generic measure of health-related quality of life, and the outcomes of the EQ-5D scale will be analyzed in a future study. Findings of the EQ VAS showed that the scores of the control /delayed therapy group dropped during the assessment times by 10 points, in contrast to the scores of the therapy group which remained relatively stable with a slight upward trend, within 5 points. The difference between the two groups was significant with the therapy group having higher scores, but there was no interaction effect. Therefore, the difference between the groups cannot be attributed to the intervention tested. It may be that as a generic measure of quality of life, the EQ-5D was not sensitive enough to pick up changes in quality of life like the SAQOL-39g did. Moreover, single item measures are less robust than multi-item scales; and visual analogue scales are not as reliable in stroke as multi-item scales (Price, Curless, Rodgers, 1999; Hilari & Boreham, 2013).

6.2.3 Therapy versus Control / Delayed Therapy Group results in the context of broader related literature

The present study makes an important contribution to the existing literature, as it is the first control study that compares ESFA therapy versus no therapy. Though direct comparisons were not possible with SFA controlled studies, as none are currently available, our findings can be considered within the context of controlled studies that reported outcomes from other speech and language therapy approaches. Brady and colleagues (2016) in the Cochrane review reported on 27 studies that assessed speech language therapy (SLT) versus no SLT. Findings of these studies are not easily comparable with our findings. Firstly, treatment intensity and dosage of therapy varied across studies. The frequency of therapy varied from an hour (CACTUS: Palmer, Enderby, Cooper, Latimer, Julious, Paterson, et al., 2012; Latimer, Dixon & Palmer, 2013) to 10 hours weekly (Wertz, 1986). The duration of the intervention varied from one session (Conklyn, 2012) to five - six months (CACTUS: Palmer, Enderby, Cooper,

Latimer, Julious, Paterson, et al., 2012; Latimer, Dixon & Palmer, 2013). Each study targeted people with aphasia at different times post-onset, e.g., Laska et al. (2011) used a very early post stroke population, in contrast to the CACTUS study (2013), which had individuals up to 29 years post onset. Furthermore, different intervention procedures and treatment protocols have been used across studies. For example, in Conklyn (2012) melodic intonation therapy was evaluated, in CACTUS (2013) computer – mediated SLT, in Laska et al. (2011) intensive Language Enrichment Therapy (LET) and in Lyon (1997) functionally – based therapy involving communication partners. Despite these differences the review concluded that SLT results in clinically and statistically significant benefits to patients' functional communication, reading, writing, and expressive language. Our results add to the evidence base for expressive language.

It is important to consider how representative our sample is of the stroke and aphasic population in order to evaluate whether our results can be generalised. Participants in this study were similar in terms of age and gender with the participants reported in the Cochrane review (Brady et al., 2016). Age range for the therapy group was from 38 to 84 and for the control/ delayed group from 44 to 79 years, with a mean of 58.38 for the therapy and 58.42 for the control/ delayed group. Age ranges in previous research reports spanned from 28 to 94 years of age (Latimer, Dixon & Palmer, 2013; Laska et al., 2011; Lincoln et al., 1984; Lyon et al., 1997; Mattioli et al., 2014; Smania et al., 2006; Varley et al., 2016; Wu, 2004) in comparison of SLT versus no SLT groups. In terms of gender, the therapy group comprised 20 men and 6 women and the control/delayed therapy group 6 men and 6 women; this difference was not significant. In our review of SFA therapy studies, 19 studies comprised 27 women and 24 men (Efstratiadou, under review). Typically, aphasia therapy controlled studies include more men than women (Latimer, Dixon & Palmer, 2013; Laska et al., 2011; Lincoln et al., 1984; Lyon et al., 1997; Mattioli et al., 2014; Smania et al., 2006; Varley et al., 2016; Wu, 2004). Comparing the demographics of our sample with people with stroke and aphasia in Greece, our participants are similar in terms of gender distribution. In Greece, stroke appears to be more prevalent in men than in women, and the mean age of stroke

onset is 70 years of age (Vasiliadis & Zirc, 2014), with an age range in the Vemmos and colleagues' stroke study (1999), of 35 to ≥ 85 years old.

In terms of aphasia severity, in the present study there was no significant difference between the two groups, with the therapy group showing mainly severe ($n=14$) and moderate ($n=7$) aphasia and the control / delayed therapy group severe ($n=5$) and moderate ($n=4$). In previous studies of SFA mostly participants with moderate to mild aphasia were treated (Boyle, 2010; Maddy, 2014; Efstratiadou, under review). Our study therefore adds to the evidence base of SFA for people with more severe aphasia.

Despite including people with severe aphasia, a substantial proportion of our participants still worked: more than half of the individuals in the therapy group (16) and eight from the control / delayed therapy group. In 2012 the Stroke Association of UK produced a report looking into the financial impact of stroke survivors and their families and reported that 69% of people with stroke of 25 to 59 years of age were unable to return to work. In Greece, things differ for employees in the public and private sector. A substantial proportion (16/36) of our sample worked in the public sector and according to Greek legislation persons with aphasia have the right to continue on full pay for as many months' post stroke as years they have worked. They are then assessed to determine their disability percentage. When the percentage is higher than 67% the person with aphasia can leave work on benefits. On the other hand, when the percentage is less than 67%, their employer has to place them in an appropriate work position in the public sector according to their abilities and qualifications. This difference in legislation may explain the large proportion of people who worked in our sample, despite the severity of their aphasia.

In conclusion, in our study ESFA therapy was effective in increasing naming ability in people with varying degrees of aphasia severity, different aphasia types, and at different times post onset. Therapy group participants showed therapy gains on the primary outcome measure of noun picture naming, in contrast to the control / delayed treatment group. Though no gains were evident in measures of communication and emotional wellbeing, gains were observed in psychosocial and overall health-related quality of life. These results were considered in the light of existing literature and factors

that contributed to their interpretation, such as limitations of the measures used, aspects of the therapy, power of the sample, were discussed.

6.3 Efficacy of ESFA Direct versus Combination Approach

The aim of the second research question was to compare and contrast the relative efficacy of ESFA, delivered via two different approaches: (i) direct (individual) and (ii) indirect combination therapy, on different domains of the WHO ICF framework, including quality of life. It was hypothesized, based on review of the literature that direct therapy will have greater benefits on participants' language skills, e.g. naming specific words (Sarno, 1991; Cermak, 2011) and that combination therapy (individual and group therapy), may improve both participants' language (though to a lesser extent than direct therapy) and functional communication, thus potentially having a greater effect on their life quality (Ownsworth et al., 2008). Therapy gains and maintenance effects are discussed in the following sections. Evaluations were completed at baseline 1 (BL1) (week 1 for IG; week 6 for CG), baseline 2 (BL2) (week 6 for IG; week 19 for CG), post – therapy (week 19 for IG; week 32 for CG), which was after 12 weeks of therapy and follow - up (FU) (week 32 for IG; week 45 for CG), which was a follow – up assessment following a period of no intervention 12 weeks post therapy.

6.3.1 Primary Outcome Measure: Snodgrass and Vanderwart Naming Test for Direct versus Combination Approach

A significant improvement on the primary outcome measure was seen after therapy and gains were maintained at the follow – up evaluation, for both approaches, i.e., the same pattern of change occurred for both approaches. There was also a small but significant change between BL1 and BL2. This could be due to familiarity with the assessment tool, as has been discussed in section 6.2.1. Participants were exposed to the Snodgrass and Vanderwart naming task four times in a period of six weeks. Spontaneous recovery cannot account for this improvement, as it typically occurs within the first 3 to 6 months' post – onset (Chapey, 2008) and the mean time of post onset was 30.55 months for the direct and 33.29 months for the combination therapy group. Although, findings of the current study are in line with the literature findings of single case/case series studies and showed that a modified type of SFA, ESFA therapy, reported positive therapy gains

and maintenance effect, findings do not support our hypothesis. We anticipated a difference between the two approaches. This was based on the different format of therapy. As Berthier and Pulvermüller (2011) suggested individual therapy is more intensive than group therapy, where practice time is divided among the group members. We therefore anticipated that individual therapy participants would make greater gains than group therapy participants. This was not the case, maybe due to our combination participants receiving two individual therapy sessions and one group therapy session per week, i.e. two thirds of their therapy sessions or half their total amount of therapy was individual. Indeed, recent evidence suggests that a combination of individual and group therapy may be a more efficacious approach. Woldag, Voigt, Bley and Hummelsheim (2017) compared constraint-induced aphasia therapy delivered in a group setting (30 hours) and group therapy with no constraints with the same intensity (30 hours) to a control group receiving individual therapy as well as group therapy (14 hours). There were no between group differences pre-treatment. Post-treatment, all groups showed significant improvements without between-group differences. In other words the control group, which had the combination approach, reached their benefits with less than half the total amount of therapy of the other two arms. Therefore the combination of individual therapy and therapy in a group setting made for the approach with the highest efficacy. Admittedly the comparison in this study was between combination and group therapy and not combination and individual therapy as in our study. Yet, this study highlights the benefits of a combination approach

Maintenance of gains was present for both approaches 3 months (12 weeks) after treatment. Maintenance of therapy gains can be affected by factors like the timing of the assessment, treatment dosage and duration (Boyle, 2010). Timing of assessment for maintenance effects is an important factor that can affect results. A maintenance effect will be higher, when the evaluation is closer to the end of the intervention rather than when it is assessed a long period after treatment. Our results could be directly compared with studies that assessed maintenance after a similar period of no therapy. We assessed maintenance 3 months (12 weeks) after treatment, as in Kristensson and colleagues

(2015) and Davis and Stanton (2005) study. Davis and Stanton also evaluated maintenance at six and 18 weeks and one year after therapy ceased. Findings of these two studies are not consistent with our results, as only one out of four participants maintained the gains made in therapy (Kristensson et al., 2015; Davis & Stanton, 2005). Comparing our findings more broadly with other studies where maintenance assessment points are variable, our findings are consistent with the body of the SFA literature, where 62.22% of participants maintain gains made in therapy (Efstratiadou, under review). A tiny decrease of naming accuracy from post – therapy to follow - up evaluation was reported in other studies as well. Coelho and colleagues (2000) reported that the effect of treatment was maintained at an 80% accuracy level one-month post – treatment and dropped to 70% accuracy at two months’ post – therapy.

6.3.2 Secondary Outcome Measures for Direct versus Combination Approach

6.3.2.1 Body Functions and Structure - Impairment - Based Level Results

6.3.2.1.1 BNT for Direct versus Combination Approach

It was hypothesized, as it was mentioned in research question one, that improvement in confrontation naming would be accompanied by improvement on a standardized measure of naming. Indeed, there was a significant main effect of time on the BNT, and pairwise comparisons showed there was a significant difference between both baselines to post-therapy and follow-up. No significant difference was reported between the two baselines and between post-therapy and follow-up. Though, the combination therapy group seemed to improve more from baseline to post-therapy, the pattern of change was similar for the two approaches, i.e. there was no interaction effect. Though not significant, this higher increase in naming post – therapy for the combination group may be related to the interaction between the group members which could also explain the higher drop in scores when the group interaction was no longer present.

These findings have added to our discussion of the BNT in relation to research question one above. They suggested that ESFA therapy can lead to generalisation. BNT

words were not treated items as those included in the primary outcome measure, therefore therapy gains following ESFA seem to have generalised to untreated items. This finding makes it more likely that the increase in BNT scores for the therapy group versus the control in our previous comparison was not significant due to lack of power. The generalisation effect was maintained for both approaches as illustrated by the outcomes of the follow – up assessment. These results also support Boyle’s (2004) suggestion that generalisation occurs from the repeated methodical accessing of the semantic system, regardless of semantic category as the BNT does not comprise items specifically within the semantic categories treated in our study.

Two studies have used SFA in a group context (Antonucci, 2009; Falconer & Antonucci, 2012) and are worth comparing with our use of ESFA in the combination approach. In these studies, each individual filled in their chart with semantic features without sharing it with the other members of the group. Once the participant had finished with the chart, group members were encouraged to discuss whether the description provided was sufficient to recognise the item. Only 2 of their 6 individuals showed an improvement on BNT scores, as opposed to our combination approach participants where a significant change was reported post therapy and it was maintenance for three months. A possible explanation of that difference may be the interactive nature of our combination approach and the added benefits of a combination approach to treatment as indicated in recent literature (Woldag et al., 2017) and highlighted above for the primary outcome measure.

In summary, in this study there was a significant effect on the BNT, an independent measure of naming, which was maintained for a period of three months after therapy ended. Studies with larger samples of participants would help demonstrate with more confidence generalisation and maintenance effects to untreated items.

6.3.2.2 Activity and Participation Level Results

6.3.2.2.1 ASHA - FACS for Direct versus Combination Approach

Functional communication of participants, in terms of activities performed, was evaluated with the ASHA – FACS. ASHA – FACS showed a significant change across time. The pattern of change for the two approaches was similar, i.e. there was no significant interaction effect, though the direct therapy group improved between post-therapy and follow up, whereas the combination therapy group remained relatively stable. Pairwise comparisons showed a significant positive difference from the baseline to the follow -up assessment point.

From the literature body of SFA studies, this study is the third, which has used an activity domain measure. Description of the studies is in the discussion chapter of the previous research question (see 6.2.2.2.1). Direct comparison is possible with Davis and Stanton's study (2005), as the same measure was used. The individuals of their study reported a positive change as our individuals. Their participant required moderate assistance in only one area from the 28 of the ASHA – FACS after the end of therapy and maintained his gains.

Results of the ASHA – FACS suggested that the significant others perceived an improvement on participants' functional communicational skills at the follow-up assessment. The fact that the difference between baselines and post therapy was not significant is in line with our findings for research question one, where significant others did not perceive a change in functional communication immediately after therapy. It may be that participants need time to integrate newly acquired skills in their communication in everyday life (Kristensson et al., 2015). Or it may be that it takes time for significant others to notice changes in participants' everyday communication.

6.3.2.2.2 Discourse “Cookie Theft” Picture for Direct versus Combination Approach

As discussed in relation to research question 1, section 6.2.2.2.2, SFA studies have reported mixed results in changes in discourse. In our study, no changes occurred for the two groups. Although in both approaches there was an increase in scores post – therapy, the increase was very small in the context of widely spread out data. A much larger sample size would be required to see if there is a trend for improvement overall in the discourse measure.

Positive changes in discourse were reported in a recent study that looked at different impairment – based therapies (Ciccone, West, Cream, Cartwright, Rai, Granger, Hankey and Godecke, 2016). They compared constraint-induced aphasia therapy (CIAT) delivered in a group setting with individual, impairment-based intervention, both administered early and daily after acute stroke. Discourse was evaluated before therapy, immediately after and at two follow – up points: 12 and 26 weeks after therapy ended. Participants from both groups showed improvement over time and interestingly scores were not significantly improved immediately after therapy but at the follow -up stage, were individuals produced more accurate and efficient verbal output. Though in our study the discourse measure was relatively stable across time, the ASHA-FACS, our other measure of communication showed a similar pattern of change.

Last but not least, our study detected significant improvements on the BNT, which suggest generalisation to untreated items. The discourse measure we used (“Cookie-theft” picture description) would also require generalisation to untreated items in order to improve. Yet, this measure did not change substantially in our study. This might be due to the fact that a naming test is less complicated than a discourse test in terms of the load on the language system and other cognitive functions. As Willsens, Vandenborre, van Dun, Verhoeven and Visch-Brink (2015) suggested, a naming test requires a straightforward word-level response, whereas a discourse test requires a coherent discourse-level response. A naming test might be less challenging for the cognitive system, whereas a discourse test is influenced by executive functioning. Furthermore, in

our study the focus was on naming therapy and not on discourse therapy, where a different strategy is required.

6.3.2.3 Personal Factors Level Results

6.3.2.3.1 GHQ-12 for Direct versus Combination Approach

In the current study, the GHQ - 12 did not show a substantial change over time or a difference between the two groups. For the combination group, descriptive statistics suggested a small drop in emotional distress post therapy, but this was likely to be driven by an outlier at that time point. We had hypothesized that given the benefits reported for group therapy (Elman & Bernstein-Ellis 1999 a & b) there could be more benefits in terms of emotional well-being for the combination group. But this was not the case. This was probably due to the different nature of our group therapy, where participants worked on an impairment-based therapy rather than on communication skills.

6.3.2.4 Quality of Life Level Results

6.3.2.4.1 SAQOL- 39g for Direct versus Combination Approach

As anticipated SAQOL-39g physical sub-domain scores remained similar across time and there was no difference between the approaches. Results of the psychosocial sub-domain did not show a significant difference across time, in contrast to findings of the previous research question where treatment had a positive impact on the psychosocial domain of the SAQOL-39g. Yet the effect size for time was large ($\eta^2p = .50$). This effect size suggests that the study may have been underpowered to pick up a significant effect of time. The effect of time may also have been masked by the pattern of change. Descriptive statistics and visual inspection of the data (figure 5.27) suggested a different pattern of change between the two approaches. Participants in the direct therapy group started with stable scores during the baseline phase (score difference .04) and increased their scores during the following assessment points by .24. Their highest scores were at the follow – up evaluation. On the other hand, participants' scores in the combination approach slightly increased at the baseline phase (.17) and increased immediately after therapy by .35 points from the highest baseline and decreased at 3 months' post – therapy by .27. Still neither the interaction nor the group effects were significant. The combination group scores followed the typical pattern expected in a treatment study, i.e. improved most post-therapy and dropped at follow-up though remaining higher than at baseline. This higher increase post – therapy may be related to the interaction with the group members which could also explain the drop in scores when the group interaction was no longer present. In contrast to the direct therapy group gains on the SAQOL-39g psychosocial domain increased similarly between BL2 and post therapy and post therapy and follow up. Still, it is important to note that these observed trends did not reach significance. A larger study would be needed to explore if there is a difference in psychosocial benefits when ESFA is delivered in individual vs. combination therapy approaches.

In the communication subdomain of the SAQOL-39g, participants' scores were relatively stable across time. Though they showed a very small increase across time, the

increase was so small that no mixed ANOVAs were carried on. There was no difference in the pattern of change between the two groups.

The overall SAQOL-39g scores showed the same pattern of change as the psychosocial domain for the two therapy approaches. The main effect of time was significant ($p=.046$) with a medium effect size, but following a Bonferroni correction to adjust for multiple comparisons, the effect was no longer significant. Pairwise comparisons did not show any significant differences between assessment points, though for both groups the largest increase in scores was from baseline 2 to post-therapy. As with the psychosocial domain, a larger study would be needed to see if there is a difference in perceived quality of life when ESFA is delivered in individual vs. combination therapy approaches.

6.3.2.4.2 EQ-5D for Direct versus Combination Approach

Findings of the EQ VAS showed that the scores of the direct approach were stable at the baseline phase, increased by a small amount after therapy and remained stable at the follow – up phase. On the other hand, combination approach scores increased during all assessment points, the highest increase was from baseline 2 to the post – therapy evaluation. As the differences were very small in a numerical scale of 0 to 100 and standard deviations were large, no further analyses were performed. As with the SAQOL-39g data, a larger study would be needed to see if there is a different pattern of change on the EQ VAS between the two therapy approaches.

6.3.3 Direct versus Combination Approach results in the context of related literature

The present study makes an important contribution to the existing literature, as it is the first control study that compares ESFA in two different conditions- direct and combination approach. Findings suggested that direct and combination participants showed therapy gains on naming, they maintained these gains and showed a

generalisation effect on naming untreated words (BNT). Significant others perceived a significant change in the communication skills of their partners with aphasia at the follow – up evaluation. Although, findings did not reach significance, a different trend was noted between the two approaches in the psychosocial domain and in the overall score of the quality of life measure (SAQOL-39g). Combination approach group followed the typically expected pattern of change; scores increased post – therapy and decreased after the end of it. On the other hand, direct approach group scores were at their highest point at the follow-up assessment. Lastly, there were no significant differences in discourse and emotional distress.

Direct comparisons were not possible with SFA studies, as none has compared direct and combination approaches. If the group approach were still a part of the study comparisons would have been possible with SFA group studies. Comparisons can be drawn with studies that compared the same therapy in different approaches for other therapies, like Ownsworth and colleagues (2008). In this study, a comparison was drawn between three therapy formats (approaches), individual, group and combination, on improving goal attainment and psychosocial function after an acquired brain injury. Thirty-five individuals received 8 weeks of 3 hours per week therapy. Their findings were compatible with our hypothesis in that individual intervention appeared to lead particularly to gains in treated areas. Combination therapy was associated with maintained gains in performance and satisfaction. Group and individual therapy reported higher gains in behavioural competency and psychological well-being factors.

Brady and colleagues (2016) in their Cochrane review reported on trials comparing group based SLT with individual SLT. None of the reported studies evaluated the same therapy in both formats. Individual participants in these studies received: a) semantic therapy (Wilssens, 2015) or b) conventional therapy (FUATAC, 2015; Pulvermuller, 2001; VERSE II, 2016; Wertz, 1981; Yao, 2005). Group intervention participants received constraint-induced aphasia therapy (CIAT) (FUATAC, 2015; Pulvermuller, 2001; VERSE II, 2016; Wilssens, 2015); were encouraged to use group discussion, recreational activities with their therapist (Wertz, 1981); or they focused on “collective language strengthening training” (Yao, 2005). A variety of assessment tools

were used, tapping on body functions and structures (e.g. receptive language, expressive language), activity and participation (e.g. functional communication) and personal and well-being factors (quality of life). Of these studies only two assessed functional communication skills and both studies (Wilssens, 2015; VERSE II, 2016) did not find any difference between the two approaches. Furthermore, each study used a different assessment tool - Amsterdam- Nijmegen Everyday Language Test (ANELT) in Wilssens (2015), percentage of correct information units per minute in a sample of discourse in VERSE II (2016). Moreover, naming accuracy was tested only in Wilssens (2015) and Pulvermuller (2001) studies, with the BNT and Aachen Aphasia Test (ATT) respectively. Although, different therapy protocols were used, outcomes were similar as in our study and no difference was detected between the two approaches. Quality of life was tested only in the VERSE II (2016) trial, with the SAQOL-39 as in our study. VERSE II study compared constraint-induced aphasia therapy (CIAT) in a group setting with individual impairment-based intervention in 20 participants with aphasia. Therapy was administered early and daily after acute stroke. Gains were assessed immediately after therapy, 12 and 26 weeks post therapy. The primary outcome was the Aphasia Quotient (AQ) from the Western Aphasia Battery, which was administrated immediately after completing the intervention. Secondary outcomes were the AQ at 12 and 26 weeks post stroke, a Discourse Analysis (DA) score and the SAQOL-39. As in our study, there was no significant difference in the pattern of change of the SAQOL-39 in the two approaches. Studies reviewed here have not reported evidence for a different pattern of change between the individual and the group format of therapy, in any of their assessment tools. Our study is different in that the same therapy, ESFA, was tested in both individual and combination therapy. Yet our findings are in line with the literature.

When considering the aphasia characteristics of the participants, aphasia severity, aphasia type and fluency status were compared with the literature. For aphasia severity, no significant difference between the two groups was found, with the largest group in both approaches being severe aphasia. In the studies included in the systematic review in Chapter 2 only three of the participants had severe aphasia, two moderate to severe, four moderate, five mild to moderate and 12 mild aphasia (21 individuals were not reported).

In terms of fluency, 27 of the 36 participants were non – fluent (18 direct / 9 combination) in contrast with the review participants where 21 were described as non–fluent and 29 as fluent. Aphasia type statistics also differed. In the studies included in the review 13 had Anomic aphasia, 12 Broca's, seven Conduction, four Wernicke's, three Transcortical Motor aphasia and one Mixed. The aphasia type of nine was not reported. In this study 14 had Broca's aphasia (eight direct / six combination), six Anomic (five direct / one combination), one Wernicke's (combination), one Conduction (combination), nine Global (six direct / three combination), and five were unclassified. Overall, the sample of this study was more severely affected by aphasia than those reported in previous studies.

The working status of participants in the two approaches showed the same pattern as in the participants in the first research question. In the direct group, 15/22 individuals worked and in the combination group 7/14. However, unlike in aphasia studies from other countries, in our study a substantial proportion of participants, $\geq 50\%$ worked.

In conclusion, both groups of participants that received ESFA therapy increased their naming ability, maintained this ability, generalised their naming skills to untrained words and showed a positive change in how their functional communication skills were perceived by their significant others. This was despite participants having varying degrees of aphasia severity, different aphasia types, and being at different times post onset. Findings suggested that the format of delivering therapy made no significant difference to the outcomes. No significant gains were observed in health – related quality of life, though effect sizes in psychosocial and overall health-related quality of life were large to medium, suggesting a larger study is needed to explore these meaningfully.

6.4 Strengths and Limitations of the Study

6.4.1 Strengths

The current study has many strengths. Firstly, this study extends the evidence base on the efficacy of a modified version of SFA. Specifically, the current research provides higher level of evidence for the SFA therapy, as it evaluated the efficacy of ESFA using a randomised design and included a control group. This is the first randomised control trial for SFA, as until now SFA treatment has been evaluated with single cases and case series studies. Randomised control trials (RCTs) are considered the design least susceptible to bias.

In a well powered RCTs, participants are randomly assigned to a treatment or control group condition, in order to reduce bias by making the groups as equal as possible with respect to all participants characteristics that may have an impact on outcomes. Thus, in theory, the only differences between the groups, are the treatment assignment and any identified differences (Hannan, 2008). This will not be the case, in underpowered or not well-randomised and controlled studies. Differences in outcomes in such cases could be due to differences in characteristics or other variables between participant groups. In our study, which was underpowered, no differences were found in demographics and aphasia related variables. Though there seemed to be a higher proportion of people with severe aphasia in the immediate therapy group (14/26) than in delayed therapy group (5/12) this did not reach significance.

We came across several challenges during the conduct of this RCT. A good quality RCT requires a long time to conduct it, has high costs and the recruitment of participants is difficult. More specifically, recruitment and data collection take a long time and it can take years before adequate statistical power is achieved. As a result of all the above challenges, RCTs are frequently underpowered, and cannot detect important differences in outcomes. Generally, this can lead to false negatives - to erroneous conclusions. Moreover, in order to detect effects of treatment in specific conditions, RCTs have inclusion and exclusion criteria that are often quite restrictive, and they do not apply

to the broader population. In the medical literature, there is evidence that RCT populations usually don't mirror the age, gender, and race distribution of the target patient population (McKee, Britton, Black, McPherson, Sanderson, & Bain, 1999; Sorensen, Lash, & Rodman, 2006). It is acknowledged that our study was underpowered; yet it managed to detect important effects. We also managed to keep our inclusion and exclusion criteria as broad as possible and therefore our sample comprised participants with a range of aphasia types, severities and times post-onset.

The inclusion of a double baseline evaluation is a further strong aspect of the design of the study. The participants were not only randomised to the therapy or control / delayed therapy group; they were also assessed using a double baseline. As Best et al. (2008) suggested studies with two or more baselines are recommended. Baselines provide us with useful information of the current state of participants and show if any changes occur independently of the therapy. Comparing changes in outcome measures across baselines to changes that occur immediately following intervention can increase our confidence that a positive effect was caused by the therapy.

Moreover, this study is the first large therapy research study for Greek people with aphasia. Previous studies of Greek people with aphasia in Greece and Cyprus were single case studies and treated mostly anomic participants (Kambanaros, 2008 & 2010; Kambanaros, & Weekes, 2012). Furthermore, this study is part of the Thales Aphasia project, where three different streams - linguistics, neuropsychology and speech – language therapy collaborated and collected different types of data from the participants. This collaboration will allow further analyses to be performed on the collated data of the different streams in the future that may answer further questions, such as the relationship between the full neuropsychological profiles of participants and their response to therapy; or whether there are specific linguistic and discourse profiles that can be drawn for participants with different types of aphasia.

The next strength comes from the selection of the participants. The Thales Aphasia project had access to participants from a range of health settings in Athens and Patras. Participants were recruited either from one of the five state hospitals in Athens and Patras or from one of the private rehabilitation centres of the city. Recruiting from a

variety of geographic settings and from both state and private hospitals / rehabilitation centres ensured social and economic biases in participant selection were minimised. In addition, the demographic characteristics of the study sample were similar to the Greek stroke population, as reported above (Vasiliadis & Zirc, 2014).

An additional positive feature of this study is the inclusion of a range of outcome measures, tapping on all WHO ICF levels. Assessment of a person with aphasia and their family / carers needed to be flexible and holistic considering whatever aspects were important or relevant to their situation. Around the world, the experience of disability differs under the influence of unique social, economic and cultural factors (Ginsburg, 2013). In this study the ICF (WHO, 2001) was used as a framework to ensure all key aspects of health were considered. Firstly, body functions and structures, the impairment - based level of the ICF was assessed with the primary outcome measure and the BNT. Then activity and participation was assessed with the ASHA – FACS and Discourse scores from the BDAE “Cookie Theft” picture. Personal factors were evaluated with the GHQ-12. Lastly, health-related quality of life was evaluated with a stroke and aphasia specific scale, the SAQOL-39g and a generic scale, the EQ-5D VAS. The use of a range of outcome measures is consistent with research findings of Worrall and associates (2011) and Wallace and colleagues (2016) who found that the goals of people with aphasia span the full spectrum of the ICF, with primary goals typically linked to the activity / participation and the body functions and structures levels. The present study provides data that can contribute in the development of a core outcome set (COS) for aphasia treatment research. COS is an approach which is being used across a variety of health fields and aims to gain consensus on research outcomes to be used across studies to allow comparisons to be drawn between them and collation of data (Wallace, Worrall, Rose, Le Dorze, Cruice, & Isaksen et al., 2016).

6.4.2 Limitations

An important limitation arises from the lack of adequate power of the study. The recruitment rate was much slower than anticipated. The initial estimate of appropriate participant numbers was based on much higher rates of recruitment at all recruitment centres. Due to unstable political and financial circumstances in Greece the recruitment was becoming slower and slower and no extension was granted by the funders of the study to allow the project to recruit enough participants.

This means that the results of the present study need to be interpreted with caution. As mentioned in the methodology chapter, for 80% power, 78 participants were required. Thales aphasia project recruited 72 participants. Moreover, power is further decreased as from the 72 participants, 58 were eligible and took part in the SLT stream and from them, 36 met the criteria to follow ESFA treatment. Not only was the study underpowered but the randomisation method was flawed as well. As the participants were randomised before SLT eligibility was checked, unequal numbers of participants resulted in the ESFA groups: of the 39 participants allocated to ESFA, 12 acted as controls, and by the end of the project 22 had the direct approach, 14 the combination approach and three had dropped out. Though small deviations from equality of the sample sizes are not detrimental (Schulz & Grimes, 2002), results of underpowered studies have to be interpreted carefully (Hackshaw, 2008). It is uncertain whether the lack of statistical significance in the comparisons made is a true finding or a false negative finding, i.e. a type II error, not getting a statistically significant result when in fact there is a true difference between groups (Biau, Devroye, & Lugosi; 2008). This limitation can be somewhat addressed by considering effect sizes. Unlike statistical tests of significance, effect sizes do not include sample size in their calculation. They are therefore often seen as tests reflecting clinical significance, as they illustrate the size of the difference between groups / conditions (Hojat & Xu, 2004). In our study, large and medium effect sizes were evident in some of our measurements. This was the case in comparing ESFA to control /delayed therapy for the primary outcome measure of naming ($\eta^2_p = .42$) and for the SAQOL-39g psychosocial and overall quality of life scores ($\eta^2_p = .12$ and $\eta^2_p = .11$ respectively) and in comparing direct to combination ESFA for the primary outcome

measure ($\eta^2_p = .49$), the BNT ($\eta^2_p = .29$), the ASHA-FACS ($\eta^2_p = .18$) and the SAQOL-39g psychosocial and overall quality of life scores ($\eta^2_p = .50$ and $\eta^2_p = .09$ respectively).

An additional negative feature of this study is the elimination of the group approach. With a group therapy only arm in the study we could have compared all different aspects of delivering therapy -as Ownsworth's (2008) study has done - and we could have tested whether group therapy in itself led to better outcomes on activity, participation and quality of life measures. The group approach was eliminated from this study, due to participants' refusal to take part in a group therapy approach. This refusal is not an unexpected reaction, as in Greece group therapy is not established. In Greece, speech and language therapy is typically delivered through individual sessions. Moreover, the Greek health insurance system, the equivalent of the National Health System (NHS) in the United Kingdom, provides only this type of treatment. Despite the fact that group therapy is economically advantageous to individual therapy (Elmans, 2007), its benefits are not recognised in Greece. However, it should be acknowledged that at the end of the therapy, many of the participants of the combination group were very positive and enthusiastic about the benefits of group therapy, including the opportunity to interact with other PWA.

6.5 Future Research Directions and Clinical Implications

A major difficulty in all studies of people with aphasia is the variable nature of aphasia. More evidence is needed in order to choose the best therapeutic approach for different clients with aphasia. The current study aimed to contribute further to the current evidence base of speech and language therapy in aphasia. To our knowledge, this is the first study that examined the efficacy of ESFA across the different domains of the WHO ICF framework, including quality of life. Hence findings, add crucial information to the existing body of literature on SFA, as well as on treatment for word finding difficulties. Directions for future research in this area are presented in this section and the clinical implications of the study are highlighted.

The results of the current study have provided positive evidence for the therapeutic protocol of ESFA and have formed the foundation for future work in this area. Data from the present study can be analysed in more depth. Firstly, data of the primary outcome measure on naming can be analysed as case studies and as case series in a similar way to the pilot of this study. Using methods as in Boyle (2004) we can explore participant responses to treated vs. untreated items, generalisation to untreated items and whether generalisation is related to the semantic categories that were accessed during treatment or seems to occur due to the stimulation of the semantic network. Participants' responses to treated vs. untreated items can be examined in a case series approach. A detailed examination of the Snodgrass and Vanderwart stimuli can be done to explore which word characteristics affect therapy gains. These factors could include variables of previous re – analysis of the Snodgrass and Vanderwart set, like those from Barry and colleague in 1997. The variables could be word frequency (high vs. low word frequency), word length (in terms of the number of phonemes or syllables), imageability (high versus low) of the word, age-of-acquisition of the word, or semantic categories of the words. This type of analysis may help us understand better the underlying mechanisms of SFA therapy.

A case series analysis can also systematically evaluate error production and whether it changes from pre to post therapy. Looking at error patterns may provide further insight into the basis of participants' word retrieval deficits and how these link to

treatment efficacy. For example, we could explore which type of word retrieval deficit, semantic errors or phonological errors, responds better to SFA and how the errors change during the treatment. Lastly, a case series analysis can illustrate whether participants with certain aphasia types or severities are more likely to benefit and show generalisation or not. To investigate the impact of personal factors, like type and severity of aphasia, a different analysis has to be done. Firstly, we have to split the participants based on their type of aphasia, according to their BDAE profile. Each aphasia group can be analysed as a case series to examine the treatment effect for that aphasia type. A similar analysis can be performed for different aphasia severities based on the BDAE, in order to find out which severity type - mild, moderate, severe - responds better to SFA. Comparisons can be driven between treatment outcomes for different aphasia types and severities by comparing their effect sizes. This analysis would also increase the clinical relevance of the present study, as it would inform further candidacy for ESFA.

Generalisation mechanisms are still not fully understood. As it has been reported in chapter 2, Boyle (2004) suggests that generalisation occurs from the repeated methodical accessing of the semantic system. On the other hand, Best et al. (2008) described generalisation when stimuli were words chosen by the PWA. A future study could compare groups receiving the same treatment, ESFA, but with different stimuli: personally relevant vs. generic as used in this study. Such a design would help unravel the underlying mechanisms of generalisation. It would also be interesting to look at whether there were differences between the two groups on secondary outcomes, such as functional communication, distress and wellbeing factors.

Lastly, in relation to the primary outcome of this study, naming accuracy, the use of another word category, such as verbs as stimuli, has never been tested in a controlled group design. In such a study, verb stimuli should be colourised pictures, comparable to the Rossion and Pourtois (2001) drawings to ensure some consistency among stimuli in order to compare results. A larger scale randomised trial with the type of stimuli controlled and how that is related to generalisation would add useful data to the evidence base on the efficacy of ESFA. Possible similarities and differences that may occur relative

to accuracy between different lexical types will also provide additional information about the organisation and function of the lexical system.

As has been raised in the limitations section above, it would be useful to replicate the current study with a larger sample size. Our confidence in the reliability of our results would increase if the current experimental protocol could be replicated with a larger number of PWA. More participants would ensure that the study is adequately powered. Such a study should be powered to explore not only the questions addressed in this project but also allow for comparison of outcomes at a group level between people of different aphasia severities and types. As above, this would inform candidacy for ESFA.

Future research could also explore further the secondary benefits of the therapy. It would be interesting to examine the elaboration process of the ESFA therapy. This may be an important factor for carrying over the gains in naming to everyday functional communication activities. In our study, elaboration was focused on the production of phrases and not in the use of these phrases in discourse or in functional communication tasks. Though partners of people with aphasia noticed some gains in their communication in the longer term, no changes in the discourse measure were found. In contrast, in other studies (Boyle, 2004; Wambaugh & Ferguson, 2007), discourse changes were recorded when training in discourse tasks was part of therapy. Therefore, the tasks used during elaboration could be investigated in future research to define which ones to see which ones are more likely to lead to benefits in discourse.

In our study, we did not find any significant differences in outcomes between the two ESFA approaches tested: individual vs. combination ESFA. Yet, there are good reasons to explore different delivery approaches further. Firstly, as indicated above, a larger study would allow us to establish with more certainty whether there are no differences in outcomes or whether our study was underpowered to detect differences in outcomes between the approaches. Secondly, future research in this area could incorporate a qualitative research component to explore participant views on different delivery modes. A sub-sample of participants could be interviewed following the

intervention to explore their views on and their satisfaction with the intervention received and its format. The experience and satisfaction of a patient plays an integral role in driving and directing quality improvement in health care (Tomkins, Siyambalapitiya, & Worrall, 2013). Last but not least, an economic evaluation and cost-effectiveness analysis would provide useful information on which approach may be more feasible to deliver when their outcomes are comparable. This accumulation of evidence on clinical efficacy, patient preferences and economic considerations would inform service provision of ESFA for people with aphasia.

In terms of clinical implications, this study provided evidence that ESFA, as delivered in Thales, is an efficacious therapy procedure to treat word finding difficulties for people with different types and severities of aphasia. The fidelity testing of the intervention also provided evidence that ESFA can be delivered consistently by different therapists. Admittedly, due to the flaws in our randomisation process and the smaller than intended sample size, this study has not provided level I definitive evidence on the efficacy of ESFA; it has however provided level II evidence. This is of significance, considering that current best practice statements for aphasia therapy for word retrieval deficits (Clinical Centre for Research Excellence in Aphasia Rehabilitation. Aphasia Rehabilitation Best Practice Statements, 2014) are based on level III/IV evidence (Wisenburn & Mahoney, 2009). Additionally, the recent Cochrane review of aphasia therapy studies did not find evidence from trials of SLT vs. no SLT to support naming therapy (Brady et al., 2016).

Considering this current level of the evidence base for word retrieval interventions, ESFA as delivered in Thales has scope for adoption in clinical practice. The resources developed for this study, such as the manual and the semantic features chart in Greek, can be made available to clinicians. Short training videos from both formats/approaches could be developed and shared on the Thales website, so that clinicians can understand better how they can implement this therapy in their clinical practice. Moreover, anecdotal evidence suggested that although participants initially had reservations about group therapy, post-therapy they were highly positive about the

combination of group and individual therapy they had received. A combination approach has added benefits for service providers and clinicians: it is cheaper and it can save busy clinicians valuable time.

It is hoped that this study will be included in the next Cochrane systematic review of aphasia therapy studies. This way, it will contribute to generating stronger evidence for the efficacy of aphasia therapy. Last but not least, as the study took place in Greece it supports evidence - based practice in Greece and promotes cross-cultural comparisons.

6.6 Conclusion

This study explored the efficacy of ESFA therapy versus no therapy and the relative efficacy of two different approaches of delivering ESFA – direct (individual therapy) versus combination therapy (individual together with group therapy) on a range of outcome measures tapping different WHO ICF domains and quality of life.

The present investigation is the first to explore the efficacy of ESFA in a randomised group design. It demonstrated that ESFA is an efficacious therapy in increasing naming ability, in contrast to no therapy. Findings showed gains in naming, communication and quality of life aspects of people with aphasia. ESFA therapy gains were observed in both approaches and were maintained over a three month follow – up period. While the benefits of this study are acknowledged there continue to be many challenges ahead. Though based on current evidence and current best practice statements, ESFA may be a useful therapy to adopt in practice, still, further research is needed to confirm the reliability of the results and allow meaningful effects to be detected on a range of outcome measures.

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