Evaluating Intensive Language Action Therapy in the NHS: a feasibility study.

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Abstract

Introduction: There is uncertainty about how best to deliver intensive Speech and Language Therapy (SLT) for aphasia efficiently under resource constraints.

Methods: This thesis: synthesised systematic review evidence to identify the intervention with the best available evidence for treating conversation difficulties; developed an intervention, programme theory and treatment protocol; tested procedures for its full-scale evaluation in a pilot randomised trial; and, tested its feasibility, acceptability and delivery fidelity.

Results: An overview of 11 systematic reviews (229 primary research studies) found Intensive Language Action Therapy (ILAT) improved conversation, could be delivered intensively and possibly efficiently. A mapping review of 31 ILAT studies identified five intervention component categories that target principles of experience-dependent learning, believed to trigger the proposed mechanism of action - Hebbian learning. A pilot study confirmed the feasibility of conducting a randomised trial of assistant/volunteer led ILAT versus usual care in NHS settings. ILAT (n=10) was compared to usual care (n=13) with conversational ability rated using the Therapy Outcome Measure's (TOMs) Impairment and Activity scales. An adjusted for baseline mean difference of -0.28(95% CI -0.79-0.23) and -0.24(95% CI -0.54- 0.59) was found on the impairment and activity scales respectively. The absence of a treatment effect could reflect the play of chance in a small sample. Qualitative research confirmed that ILAT is acceptable to patients (n=13) and feasible for SLT-facilitated assistants (n=3) and volunteers (n=2) to deliver. Fidelity to delivery of most aspects of the intervention was good, except for provision of the target therapy dose and prompting patients to expand their language use.

Conclusion: ILAT is an intensive conversational therapy for aphasia with the potential to be delivered efficiently by assistants/volunteers, and is acceptable to consumers and health professionals. Further preliminary research is needed on outcome measure assessment, acceptability and delivery of intended dose prior to a definitive trial.

List of abbreviations

AAT Aachen Aphasia Test
ACT Action Communication Test
BDAE Boston Diagnostic Aphasia Examination
BNT Boston Naming Test
CADL -2 Communication Activity of Daily living - 2
CAL Communication Activity Log
CAT Comprehensive Aphasia Test
CEI Communicative Effectiveness Index
CEP Communicative Effectiveness Profile
CIAT/ILAT Constraint Induced Aphasia Therapy/Intensive Language Action Therapy
CINAHL Cumulative Index to Nursing and Allied Health Literature
CIU Correct Information Unit
COM-B Capability, Opportunity, Motivation – Behaviour model
COAST Communication Outcome after Stroke
COAWT Controlled Oral Word Association Test
CONSORT Consolidated Standards of Reporting Trials
CReDECI Criteria for Reporting the Development and Evaluation of Complex Interventions
CST Consent Support Tool
DIL Daily Intervention Log
GRADE Grading of Recommendations, Assessments, Development and Evaluation
ISRCTN International Standard Registered Clinical/soCial sTudy Number
LAG Language Action Game
MEDLINE Medical Literature Analysis and Retrieval System Online
M-MAT Multi-Modal Aphasia Therapy
N/A Not applicable
NGA Norwegian basic aphasia test
NHS National Health Service
NIH-BCC National Institute for Health Behaviour Change Consortium
NR Not reported
NRCT Non-Randomised Control Trial
PACE Promoting Aphasics' Communication Effectiveness
PALPA Psycholinguistic Assessments of Language Processing in Aphasia
PPVT Peabody Picture vocab test
RCT Randomised Control Trial
SFC Semantic Fluency Test
SLT Speech and Language Therapist
TIDieR Template for Intervention Description and replication
TDF Theoretical Domains Framework
TFA The Framework of Acceptability
TOM Therapy Outcome Measure
TPO Time post onset
TROG Test for Reception of Grammar
TT Token Test
VAL Verbal Activity Log
VIT Verb Inflection Test
VOST Verb and Sentence Test
WAB Western Aphasia Battery
WAB AQ Western Aphasia Battery Aphasia Quotient

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Declaration

I, Nicola Crook, confirm that the Thesis is my own work. I am aware of the University's Guidance on the Use of Unfair Means (www.sheffield.ac.uk/ssid/unfair-means). This work has not been previously been presented for an award at this, or any other, university.

Chapter One: Background

This chapter defines aphasia, and its impact on communication and the lives of people living with aphasia. It includes a discussion of current rehabilitation interventions used for the treatment of aphasia, theoretical understandings, the research evidence and practical considerations of treating aphasia in the context of the National Health Service in the United Kingdom. The chapter identifies that interventions for the treatment of aphasia are best delivered intensively, efficiently and should target communication in conversation to remediate the impairment caused by aphasia improving the activity, participation and quality of life of people living with aphasia. This thesis plans to identify and evaluate an intervention that meets these criteria and the chapter concludes with the thesis aims.

1. Introduction

Aphasia is a term used to describe an acquired communication impairment following neurological damage. Stroke is the most common cause of aphasia with approximately one third of stroke survivors acquiring aphasia (1). Aphasia has a varied impact on all communication skills such as speaking, listening, reading, writing, gesture and using numbers. The disruption of these fundamental communication skills by aphasia has a wide reaching impact on activities of daily life and social participation (2). As a consequence, people with aphasia suffer depression (3), social isolation (4) and, loss of identity as they are unable to fulfil previous social and vocational roles (5). Estimates of the prevalence of depression in people with aphasia range from 62-70% (6). People with aphasia can receive Speech and Language Therapy to improve communication. This chapter provides a definition of aphasia within the International Classification of Functioning Disability and Health (ICF)(7) and a discussion of the theoretical understandings, research evidence and practical considerations of current interventions provided for treating aphasia in the NHS. Following this overview the rationale and background for the research objectives of this thesis are presented (see section 1.7.1 Research objectives for this thesis).

1.1 Definition and prevalence of aphasia

Aphasia, also referred to as dysphasia, is an acquired impairment of language function following brain damage. The word aphasia originates from the Greek “a” meaning without and “phásis” meaning speech. Thus, aphasia means without speech (8). Papathanasiou, et al (2003) define aphasia 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 (pg.4)(9)*"*

The most common cause of aphasia is stroke, mainly to the left hemisphere. However, aphasia can also be acquired through traumatic brain injury or as a consequence of progressive neurological conditions such as dementia and can be a disorder in its own right as in Primary Progressive Aphasia (1). In England one in six people will have a stroke in their life time. Approximately 100,000 people will have a stroke every year (10) and around 30% of those people who have had one stroke will experience another. Stroke is the leading cause of death and disability in the UK and roughly one third of stroke survivors will have aphasia (11). Aphasia affects more than 350, 000 people in the UK (1).

All aspects of language including reading, writing, understanding language, speaking, gesture and using numbers can be affected by aphasia (12). The individual profile of aphasia across these language modalities varies per individual, as does the severity of aphasia ranging from occasional word finding difficulties to no effective means of communication at all (1). Recovery from aphasia also varies between individuals with the size and place of the neurological damage (12) as well as psychosocial factors affecting the course and degree of recovery(1,13). Most people with aphasia will make some degree of recovery however many continue to experience difficulties associated with aphasia for months and years after its onset. Research indicates that continued recovery is possible years after stroke (14).

1.1.2 Classifying aphasia

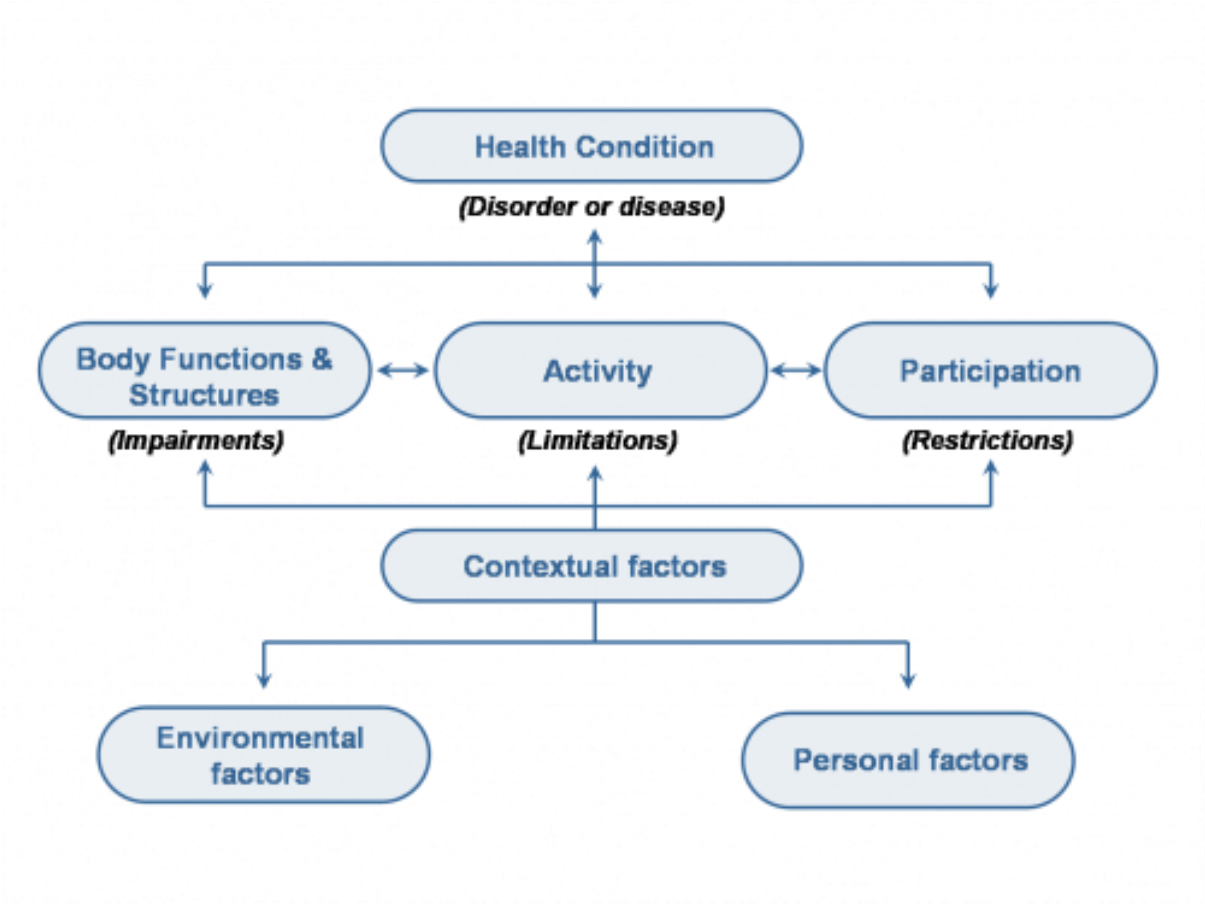
Damage to any of the neuroanatomical areas associated with language production and processing, and those networks that connect them can cause aphasia. The neurology of language is complex and diversely spread throughout the brain and therefore damage to many areas of the brain can cause aphasia with varying characteristics (12). Historically, localisation theory proposed that language is processed in specific and discrete anatomical areas of the brain however, advances in brain imagining have expanded understanding of language processing and production demonstrating that both right and left hemisphere neural networks, as well as distant areas not previously associated with language such as inferior and anterior temporal cortex and the basal ganglia and thalamus, are activated during language tasks (15). Over the development of aphasiology there have been many attempts to delineate or classify aphasia into specific types in the hope that this would lead to type specific treatment in clinical practice, provide better insight into the underlying nature of aphasia and allow valuable information about the communication of people with aphasia to be efficiently

communicated. Many methods have been used to attempt to place aphasia in types such as, the location of neurological damage as in the Boston Classification System. For example Broca's (non-fluent with speech with lots of pauses) or Wernicke's (fluent with lots of sound errors or nonsense words) (16) aphasia. However, the overlap of symptoms or language function between these types makes classifying aphasia in this way very unclear (17). Another method used to type aphasia is to describe the psycholinguistic features of aphasia such as semantic (difficulties accessing the meaning or names of items (18)) or phonological (sound errors and nonsense words) aphasia (19). Broader terms such as expressive (difficulties speaking) or receptive (difficulties understanding language) aphasia have also been used (20). However, people with aphasia often present with mixed symptoms (21) or variability of performance across tasks (22). Due to this variability, classifying and categorising aphasia has been an ongoing endeavour that continues to spark debate. Furthermore, over the natural course of aphasia recovery the type of aphasia may change. Therefore, typing is considered unnecessary by some researchers and aphasia is seen as a single unitary disorder encompassing all language modalities to individual and varying degrees (17). Whilst classifying may be important to help understand a person's aphasia, clinicians do not tend to treat a type of aphasia but instead target the symptom or language deficits presented by the person with aphasia (17).

1.2 The impact of aphasia and the ICF

The International Classification of Functioning, Disability and Health (ICF) model describes the impact of a condition on the person and is a useful tool for discussing the full impact of aphasia. The World Health Organization defines "health" as "*the complete physical, mental, and social functioning of a person and not merely the absence of disease*" (7,23). The ICF model (see Figure 1) supports the examination of a condition from several different perspectives: body function and structure, activity, participation, environmental and personal factors. This model encourages all stakeholders in the diagnosis and treatment of aphasia to look beyond the condition and consider the context of the person with aphasia. Therefore, it advocates selecting assessments and interventions to address not just the bodily impairment of aphasia, but also how to expand or increase the types, varieties or amount of activities that people with aphasia can engage with, how independently people with aphasia participate within these activities, how the environment around those with aphasia can be altered to best support participation and activity and finally what impact personal factors might have on participation and activity (7). Thus, considering the person with aphasia within the context of everyday life and giving some indication of the quality of life of the person with aphasia and their families is important. Aphasia impacts all domains of the ICF and significantly impacts the overall quality of life of the person with aphasia (24). The next section provides a discussion of the impact of aphasia on each domain of the ICF.

Figure 1 The International Classification of Functioning, Disability and Health model (7)



1.2.1 Body Structure and Function

In aphasia, damage to the brain impacts the use of language processing and production across language modalities of reading, writing, speaking, understanding language and using numbers. Research indicates that impairment caused by aphasia can be remediated through therapeutic environments and interventions that encourage neural rewiring and experience dependent learning (25–27). A recent Cochrane review found that interventions for aphasia can reduce the severity of impairment experienced by people with aphasia (28).

1.2.2 Activity and Participation

The activity domain encompasses everyday activities and routines and the participation domain identifies the person's involvement in everyday situations and social and vocational roles (7). These domains are heavily interwoven in practice and will be discussed jointly throughout this thesis. Aphasia can make everyday tasks such as reading or writing a letter, having a conversation, talking on the telephone and making simple wants and needs understood difficult or impossible. Aphasia can

restrict the activities of people with aphasia limiting with whom, how, where and when people with aphasia can or do participate in activities and situations (29). Research indicates that people with aphasia participate in fewer activities than age matched peers and express dissatisfaction with the number of activities in which they participate. 50% of people with aphasia stated they would like to engage in more activities (30). People with aphasia report being unable to return to many of their usual activities such as watching TV, reading, visiting friends or family or using the internet as the difficulties associated with aphasia prevent or dampen the enjoyment once experienced by these activities (31). Fewer people with aphasia return to work than those who have suffered a stroke without aphasia (32).

1.2.3 Environmental Factors

Environmental factors are those that are outside the control of the person with the condition such as cultural beliefs, family and other relationships, employment opportunities, printed communications, signage, internet design (33) and government or agency policy and laws (34). These factors could be considered the context in which the person with aphasia with their body structure/function attempts to complete activities or participate in daily life (7). These factors can be supportive or not (35). For example, a person with mild difficulties finding the words to say may have a very strained relationship with a partner if that partner interrupts, interprets and does not allow the person with aphasia time and support to find their own words. Conversely, a person with severe aphasia may well be able to get back to work if the employer is flexible and supportive, allowing the person with aphasia to complete tasks that are within the body function/structure capability, and providing the extra supports to compensate for limitations.

1.2.4 Personal Factors

Personal factors could be considered the internal context from which a person with aphasia approaches activity and participation, including age, gender, education, beliefs, coping strategies, personality, self-esteem etcetera (29,34). Estimates of the prevalence of depression in people with aphasia range from 62-70% and whilst aphasia was not a predictor for distress in people who had suffered a stroke, 93% of people with aphasia report feelings of distress compared to 50% of those without aphasia(6). These personal factors can have a profound impact on perceived quality of life and rehabilitation outcomes of people with aphasia (36).

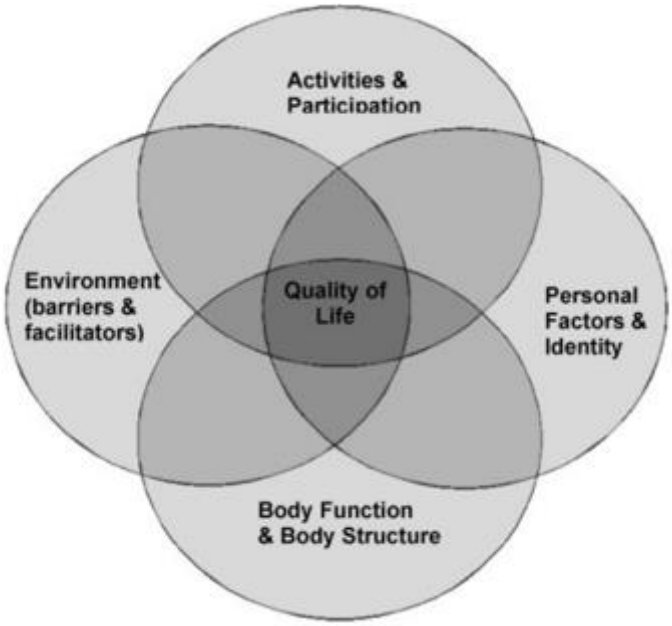
1.2.5 Quality of life and the ICF

Quality of life is considered multifactorial and includes the health, comfort and happiness experienced by an individual. It is those things identified by the individual that are essential for a good quality of life. The World Health Organisation defines quality of Life 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 (37)*".*

Quality of life is not conceptualised within the ICF (29). Kagan et al. (38) adapted the ICF adding the concept of quality of life in the Framework for Outcome Measurement (FROM). FROM is shown in Figure 2 and it highlights the dynamic and overlapping impact of the ICF domains and how these domains form quality of life (38).

Figure 2 Framework for outcome measurement (FROM)(38)



A systematic review identified depression, communication disability, engagement in activities and diminishing social networks as the factors that affected quality of life for people with aphasia (39). These factors are widely spread across the domains of the ICF. Given the wide ranging and devastating impact of aphasia on the lives of those living with the condition (2,29) it is important that treatment addresses all domains of the ICF in order to best impact the quality of life of people with aphasia (24). The following discussion of the treatment of aphasia will be framed by the ICF domains.

1.3 Treatment of Aphasia

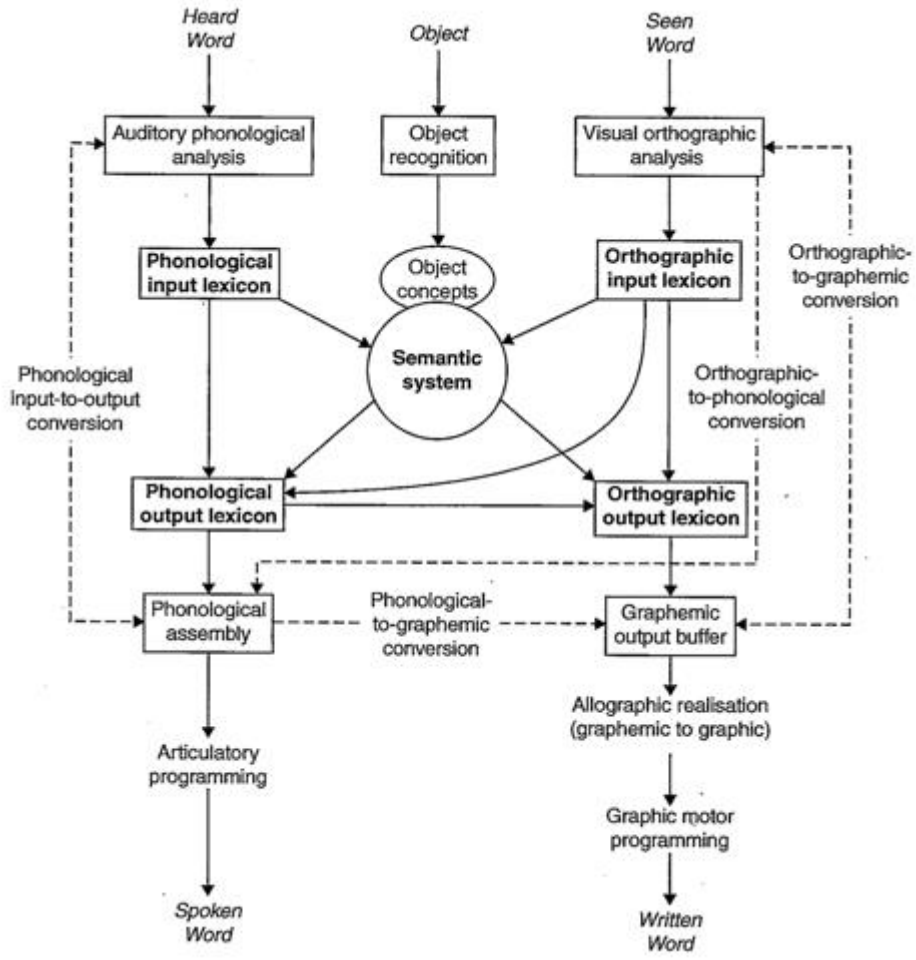
A variety of interventions have been developed to treat aphasia. Interventions have been developed following different theoretical models of language production, principles of neuroplasticity, targeting

different aspects of language impairment and methods of rehabilitation. The following sections discuss language and aphasia highlighting the different theoretical standpoints and examples of interventions for aphasia based on each theory.

1.3.1 Interventions underpinned by models of language processing and production

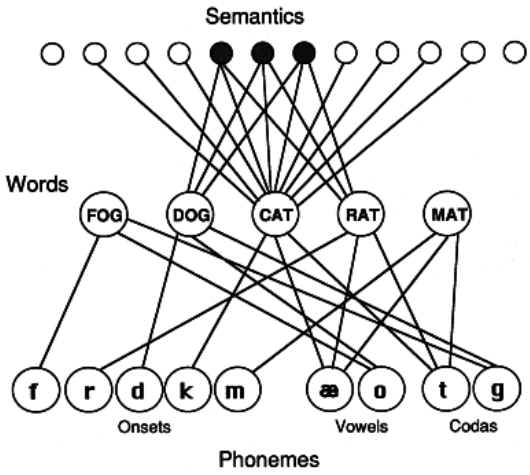
Interventions have been predominantly driven by psycholinguistic representations of language processing (40). These interventions attempt to treat specific segments or processes within the models of language processing described by Figure 3 (41). There are several models of speech production and processing ranging from 'box and arrow' models to connectionist models. The process of how the human brain understands and produces language is complex. To say a word the object must be recognised, its name identified and correctly produced (42). Figure 3 shows a model for single word processing (41). This model divides language into four modalities; understanding spoken language, reading, speaking and writing and operates in a top down, unidirectional way. This simplified model allows SLTs and researchers to diagnose and analyse the communication abilities of people with aphasia and select interventions to treat aphasia.

Figure 3 Cognitive Psycholinguistic Model of Single words (41)



However, this model has several limitations in that it cannot be used to explain the complexities of constructing sentences or indeed combining sentences into discourse or conversation, which is ultimately what is needed for effective communication (43,44). Therefore, connectionist theories of neural processing are attempting to understand the complexities of communication and language using computational modelling. These complex models state that simple neural units contain discrete information termed 'micro-features' that together are activated to form a larger nodes. These units work in parallel, in cooperation or competition and are distributed across the neural network of the brain. Nodes are either excited or inhibited by an external input and or interactions between connected nodes. Nodes are considered to collectively represent different or specific information to form a layer and these layers form the structure of the model (45) as seen in Figure 4 (46). Several connectionist models such as the Aphasia Model (46), Foygel and Dell's Interactive Model of lexical Access (44) and the Two-Step Model of Lexical Access (47) demonstrate, using error analysis and latency in word production, that these modules are bi-directional allowing layers further along the neural network to influence the outcome of previous modules/layers. Allowing an intricate and complex neural network to operate with flexibility in the processing and production of language (48). The connectionist model is much more flexibly applicable to the full range of linguistic functions from single word production to complex sentences, including reading and writing. Further the connectionist models account for the variability in consistency and rules of a language demonstrating a model that is able, through its connections and hidden units to learn the exceptions evident in language for example in inconsistent past tense as in drink/drank or exceptions in spelling as in yacht (44). However, these models have not yet made an impact on the diagnosis and treatment of people with aphasia (49).

Figure 4 Dell Aphasia model of language production (46)



Language can be impaired at any stage of the input or output processes as described above. For example, an inability to understand spoken words could be an impairment of the auditory phonological analysis, the phonological input lexicon, the semantic system or the interactions and communications between these processes. Therefore, it is possible to have a very specific difficulty within one area of the perception and processing of language (41); however more commonly several processes are involved in impaired language (21). For instance, there are several interventions such as Semantic Feature analysis (50), and BOX therapy (51) that aim to improve access to the Semantic System depicted in the model in Figure 3. These interventions focus on tasks that require making judgments about semantic relationships, for example sorting items into categories such as animals or plants, matching spoken words to pictures (57) and identifying the features of an item such as describing a banana as a yellow, fruit that is long and curved (50). Interventions have also been developed to target the phonological processes of the model such as using repetition and copying and giving cues about the sounds or phonemes within a target word (52–54). These interventions often only target single words (41). Therefore, additional interventions have been developed to target language beyond the single word such as grammatical structures of sentences or discourse and interventions for reading and writing.

1.3.2 Cognitive linguistic approaches to aphasia intervention

Many interventions for aphasia utilise cognitive linguistic approaches and the principles of neuroplasticity drawing on the capacity of the central nervous system to adapt to external and biological factors including behavioural training described as experience-dependent plasticity (55). The underlying assumption of experience-dependent plasticity is that the brain is able to change, that it is capable of structural and functional plasticity. Experience-dependent plasticity occurs as the neural networks are rewired and reorganised through learning that can be achieved during interventions (56) resulting in language recovery. These therapies attempt to incorporate one or more of the ten principles listed in Table 1.

Table 1 Principles of experience-dependent plasticity (55)

Principle	Description
1. Use It or Lose It	Failure to drive specific brain functions can lead to functional degradation.
2.Use It and Improve It	Training that drives a specific brain function can lead to an enhancement of that function.
3. Specificity	The nature of the training experience dictates the nature of the plasticity.
4.Repetition Matters	Induction of plasticity requires sufficient repetition.
5. Intensity Matters	Induction of plasticity requires sufficient training intensity.
6. Time Matters	Different forms of plasticity occur at different times during training.
7. Salience Matters	The training experience must be sufficiently salient to induce plasticity.
8. Age Matters	Training-induced plasticity occurs more readily in younger brains.
9. Transference	Plasticity in response to one training experience can enhance the acquisition of similar behaviors.
10. Interference	Plasticity in response to one experience can interfere with the acquisition of other behaviors.

Interventions based on experience dependent learning attempt to create therapeutic environments or contexts that support individual principles. For example, interventions that attempt to target principle two, 'use it and improve it', would create a therapeutic task that mimics the language function being targeted; what is practiced is improved. For instance, if being able to use words in sentences was the goal of the intervention then practising single words would not necessarily improve the ability to speak in sentences. Interventions such as Intensive Language Action Therapy (57) and Multi-Modality Aphasia Therapy (58) attempt to improve the functional communication of people with aphasia through the use of language games that mimic everyday communication such as requesting an item or planning an event. Similarly the principle of salience states that materials and interventions must be personally relevant to the patient in order to achieve good outcomes (55). Mixed results have been found in the aphasia literature examining transference, the principle that training one language behaviour will result in improvements in another. A principle that has developed from this literature is that generalisation is more likely to occur to untrained language behaviour that is similar to the one being trained. For example generalisation is more likely to occur to words or sentences that are from the same semantic or syntactic category. Also, treating more complex language behaviours is more likely to generalise to simpler behaviours rather than simple behaviours extending to the more complex (59). Many interventions have also incorporated the intensity matters principle by providing massed practice, intensive schedules and large doses of intervention. There is a body of literature suggesting that intensively delivered interventions are more beneficial in the treatment of aphasia than distributed schedules (28,60). However, this principle is modulated by the timing matters principle in that early, intensive interventions may be

detrimental and that complete non-use is also detrimental. Therefore, it is proposed that the treatment schedule should change and become more intensive over time. Despite the available evidence further research is needed to examine how these principles interact with each other and other factors such as lesion location, patient motivation and cognitive skills (59). As yet there is no clear understanding of the ideal conditions that would optimise neural plasticity and aphasia recovery (61).

1.3.3 Functional, social and compensatory models of intervention

The interventions in Section 1.3.1 and 1.3.2 have targeted the underlying language impairment caused by aphasia focusing on the body, structure and function domain of the ICF (7). Functionally or socially focused interventions approach the treatment of aphasia in the context of the daily living activities of people with aphasia. The primary focus of these interventions is to encourage people with aphasia to re-engage in life and to modify the environment, train those around the person with aphasia or encourage the use of compensatory strategies that improve the participation of people with aphasia in activities (62). Functionally oriented interventions include conversation partner training, supported conversation, communication support groups and alternative and augmentative communication. Compensatory strategies include gesture, drawing and using pictures or communication boards, books or technological devices to augment or replace spoken communication (63). These interventions target the domains of activity, participation and contextual factors (29). Psychological support and social support and stimulation, such as life coaching targets the personal and environmental domains of the ICF (64). Galletta and Barrett (62) argue that no one domain of the ICF is more important than another proposing that delivering both impairment and functionally oriented interventions provides the optimal treatment program for people with aphasia.

It is important to note that these interventions underpinned by very different theoretical standpoints are rarely delivered in isolation. Ideally a variety of interventions are provided to people with aphasia spanning these theoretical understandings to provide a tailored package of intervention that holistically address the impairment, activity, participation, environment, personal considerations and quality of life of people with aphasia.

1.3.4 Perspectives and Goals of People with Aphasia

An essential consideration in the development of interventions for people with aphasia is their personal goals and perspectives. Several studies have examined the quality of life, perspectives and goals of people with aphasia (39,65,66) including an international study that used a nominal group technique to identify and rank desired treatment outcomes of people with aphasia and their family

members. The themes identified included: improved communication; increased life participation; and, recovered normality (67).

The theme 'improving communication' encompassed the concepts of speaking in more complex sentences, improving participation in conversation and having more complex conversation including discussions in groups or over the telephone. Also people with aphasia identified that they wanted to be able to communicate more independently, to comprehend conversations, keep up with changes in topic and have normal meaningful conversations that were beyond communicating basic wants and needs (67). This confirmed the work of Worrall et al. (2011), (24) who explored the goals of people with aphasia according to the ICF (34) finding people with aphasia wanted to communicate their opinions and to have greater autonomy and engagement in social situations and activities.

Wallace et al. (2017) also reported the theme 'increased life participation' which included the concepts of being able to increase social life and maintain existing friendships (67). This confirmed previous studies which found people with aphasia reported friendships and feeling integrated into a social circle were negatively affected by aphasia (65)(24), had conversations with fewer people and had smaller social networks (68). Loneliness and low satisfaction with social networks was found to contribute to long-term psychological distress (39) leaving people with aphasia feeling socially isolated due to aphasia (69). The primary mode of communication in daily life is conversation and is where the difficulties caused by aphasia have the most negative effect (70). Parr et al. (1997) stated that

"language is the currency of relationships" (p.44) (31)

recognising language is the means of sharing thoughts, feelings and experiences. Being unable or struggling to make, maintain and participate in conversation has a negative impact on the ability to maintain and build friendships and social networks.

Wallace et al. (2017) also reported a desire for 'recovered normality', which was expressed as regaining, maintaining and improving communication to regain pre-aphasia identity and confidence. Again, Worrall et al. (2011) also found this theme of wanting to return to normality and be rid of the difficulties associated with stroke and aphasia (24).

Cruice et al. (2010) reported that interventions for aphasia would ideally focus on spoken communication through interventions that target conversation impairment (66). People with aphasia were found to have social goals such as having conversations with family and friends (24). Maher, et al.et al. (2016) completed a study were participants received an intervention that encouraged compensatory and alternative or augmentative communication approaches and

compared it with another that constrained the participants to only spoken language. Participants chose to use the speech modality more often even in the unconstrained version (71). Again emphasising the desire of people with aphasia to return to normality and use spoken communication as they previously had. Cruice et al. (2006), (72) reported that participants were preoccupied by their inability to speak and Worrall et al. (2011) reported people with aphasia had intense feelings of frustration and hopelessness at not being able to talk (24). In my own clinical experience of working with people with aphasia, communication aids and devices or compensatory strategies such as writing or gesture have not been readily taken up by those whom I have worked with. One family member commented that their relative would use writing with me during SLT sessions but would only focus on talking in everyday conversations.

1.4 Cochrane review findings

Given this breadth and diversity of interventions for aphasia it is important to determine their effectiveness. A recent Cochrane review examined the effectiveness of interventions for aphasia with several key findings summarised in Table 2. The first set of comparisons was based on 27 studies comprising 1620 people with aphasia. Comparisons revealed that when functional communication was the outcome; SLT vs.no SLT favoured SLT with moderate certainty; SLT vs. no SLT after 6 month follow up showed an equivocal result with very low certainty. Benefits were found for functional use of language, language comprehension and production when the comparison was no intervention however, these benefits may not result in long term changes (28). Table 2 summarised the findings from the Cochrane review of interventions for aphasia.

Table 2 Summary of findings from Cochrane review of interventions for aphasia

Outcomes	SLT comparison	Number of participants (trials)	Relative effect (95% CI)	Direction of effect	Quality of the evidence (GRADE)
Functional Communication	SLT vs. no SLT	376 participants (10 trials)	SMD: 0.28 (0.6-0.49)	Favours SLT	⊕⊕⊕∅ Moderate
	SLT vs. no SLT (6 months follow up)	11 participants (2 trials)	SMD: 0.19 (-0.80-1.18)	No evidence of benefit or harm	⊕∅∅∅ Very low
	High-intensity SLT vs. Low intensity	84 participants (2 trials)	MD: 11.75 (4.09-19.40)	Favours high intensity SLT	⊕⊕∅∅ Low
	Group SLT vs. one-to-one SLT	46 participants (3 trials)	SMD: 0.41 (0.19-1.00)	No evidence of benefit or harm	⊕∅∅∅ Very low
	Computer mediated vs. professional SLT	55 participants (3 trials)	SMD 0.44 (-0.10-0.98)	No evidence of benefit or harm	⊕∅∅∅ Very low
	Constraint-Induced Aphasia therapy vs other SLT	126 participants (3 trials)	SMD: 0.15 (-0.21-0.50)	No evidence of benefit or harm	⊕⊕∅∅ Low
Severity of impairment	High-intensity SLT vs. Low intensity	187 participants (5 trials)	SMD: 0.38 (0.07-0.69)	Favours high-intensity SLT	⊕⊕⊕∅ Moderate
	Computer mediated vs. professional SLT	122 participants (4 trials)	SMD: 0.15 (-0.21-0.50)	No evidence of benefit or harm	⊕⊕∅∅ Low
Receptive Language	SLT vs. no SLT	399 participants (9 trials)	SMD: 0.6 (-0.15-0.26)	No evidence of benefit or harm	⊕⊕∅∅ Low
	SLT vs. no SLT (6 months follow up)	111 participants (2 trials)	MD: 1.38 (-1.39-4.15)	No evidence if benefit or harm	⊕∅∅∅ Very low
Expressive Language	SLT vs. no SLT	275 participants (7 trials)	SMD: 0.14 (-0.10-0.38)	No evidence of benefit or harm	⊕∅∅∅ Very low
	SLT vs. no SLT (6 months follow up)	111 participants (3 trials)	SMD: 0.07 (-0.59-0.73)	No evidence of benefit or harm	⊕∅∅∅ Very low

SLT= Speech and Language Therapy GRADE=**Grading** of Recommendations, **Assessment**, Development and Evaluations CI=Confidence Interval SMD = Standard Mean Difference

MD= Mean Difference

A further 38 studies compared differing therapy regimens or delivery modes within this review. Efficient methods of delivering interventions for aphasia showed that: group SLT vs. one-to-one SLT had an equivocal result with very low certainty; computer mediated SLT vs. professional SLT showed an equivocal result with very low certainty when functional communication was the outcome and a small increase to low certainty was found when severity of aphasia was the outcome; volunteer facilitated interventions showed an equivocal result on all comparisons. High intensity vs. low intensity SLT favoured high intensity SLT with low certainty when functional communication was the outcome however moderate certainty was found when severity of aphasia was the outcome. No evidence of benefit or harm from intensive therapy was found when receptive and expressive language were the outcome. There was no evidence that allowed one type of intervention to be recommended above another (28).

The authors of the review concluded that many hours of therapy delivered at high intensity showed improvements in functional communication and reduced the severity of aphasia. However, more people withdrew from intensive treatments. Furthermore, the quality of the studies or their reporting was poor. Therefore, there is an urgent need for further high quality studies that evaluate interventions for aphasia examining the delivery methods, dose and intensity (28).

1.5 Service delivery of interventions for aphasia within the NHS context

In the National Health Service the demand for Speech and Language Therapy intervention for aphasia is overwhelming Speech and Language Therapists (SLT). SLT resources are usually insufficient to provide high doses of intensively delivered interventions to best support people with aphasia as principles of neuroplasticity and current evidence would suggest. The 2015 Sentinel Audit for stroke shows that patients receive on average 10 minutes of therapy a day well below the recommended amount of 45 minutes a day 5 days a week during their inpatient rehabilitation (73). Once discharged from acute care, on average people with aphasia are only receiving one hour every two weeks of SLT intervention on the NHS (74), which continues to be much less than is recommended (28). Furthermore, many services are time limited and can only offer interventions for the first few months following the onset of aphasia contrary to research findings that people with aphasia can continue to improve for years post onset (14). These limitations in intervention delivery are contrary to the weight of evidence provided by the literature(28,75). Therefore, interventions that can be efficiently delivered need to be explored.

1.7 Conclusions

This background chapter has established that aphasia has a wide ranging impact on the quality of life of people with aphasia (66), it can be understood and classified in a variety of ways (17), and treated

with numerous therapies based on different theoretical understandings. The theoretical underpinnings, the types of intervention used to remediate aphasia and the research evidence have been briefly discussed. People with aphasia report that the impact of aphasia on conversation and relationships is the most devastating aspect of aphasia (66) and that being able to autonomously maintain relationships through conversation rather than relying on support from communication partners or compensatory strategies is important to them (24). They want to independently have normal, meaningful conversations (67) and may have a preference for conversing through talking rather than compensatory strategies. Therefore, treatment programs that target aphasia across all aspects of the ICF domains and target conversation may be optimal for improving the quality of life for people with aphasia. The evidence to date suggests that people with aphasia benefit most from high doses of intensively delivered SLT interventions (82). However, SLT in the National Health Service is often only delivered once or twice a week (28) and therapy is also often time limited which is contrary to evidence that people can continue to improve for years' post onset (76). Therefore, SLTs working within the NHS require efficient ways of delivering high doses of intensively delivered, efficacious interventions that target communication in conversation to people with aphasia, irrespective of when the timing of the aphasia onset. The Cochrane review identified the need for more high quality RCTs that evaluate interventions for aphasia examining the delivery methods, dose and intensity (28).

1.7.1 Research objectives for this thesis

This thesis aims to:

6 identify an intervention for aphasia that targets conversation, can be intensively and efficiently delivered, and has the best evidence to date;

7 review how the mechanism of action for the intervention that targets conversation has been described in the literature;

8 describe how to operationalise the intervention that targets conversation to be intensively and efficiently delivered in the NHS;

9 determine if it is feasible to evaluate the intervention that targets conversation and can be intensively and efficiently delivered in a randomised control trial; and

10 determine if it is feasible and acceptable to deliver the intervention that targets conversation and can be intensively and efficiently delivered in the NHS.

Chapter Two: Identifying an intervention for aphasia that targets conversation, can be intensively and efficiently delivered, and has the best evidence: a review of systematic reviews

Evidence suggests that people with aphasia benefit most from intensively delivered SLT interventions that target conversation months or years after the onset of aphasia. Therefore, this chapter reviews the evidence for the effectiveness of such aphasia interventions through the collation and examination of systematic reviews of aphasia interventions with the aim of identifying an intervention to study within the NHS context.

2.1 Introduction

Chapter one concluded that people with aphasia benefit most from interventions that can be delivered intensively and can continue to improve with therapy months and years post stroke (28). However, resources in the NHS mean that SLT interventions are often delivered once or twice per week and are often time limited to weeks or months post stroke (74). People with aphasia report that they want to use spoken language better in conversation(66) and the ability to voice opinions and maintain social networks improves the quality of life of people with aphasia(69), so interventions for aphasia should target conversation with the aim of improving spoken language (30,71). Therefore, SLTs working in the NHS require efficient ways of delivering high doses of intensively delivered efficacious interventions that target spoken language impairment which impacts conversation long term after aphasia onset. This chapter focuses on the first thesis aim to identify an intervention for aphasia that improves conversation through targeting spoken language, is resource efficient, can be delivered intensively and has the best available evidence to date.

The objectives were to:

1. identify interventions for aphasia that improve conversation by targeting spoken language and have been delivered intensively, through literature review;
2. identify methods of delivering interventions that may be efficient for the NHS that have been described in the literature; and,
3. review the evidence for the interventions identified.

Definitions of concepts required to examine the above objectives for each intervention were as follows:

1. Targeting conversation was defined as interventions that aim to impact conversation through therapeutic, compensatory or training activities;
2. Impairment based interventions were defined as those interventions that aimed to remediate aphasia through directly improving impairments (body structure and function of the ICF (36)) such as improving naming, receptive language skills or aphasia severity, and not communication/social based interventions which were defined as those interventions that attempt to support the person with aphasia to communicate by any means including compensatory strategies, creating supportive communicative environments and training communication partners;
3. Mode of delivery and professional and non-professional delivery were extracted to determine if an intervention could be delivered in an efficient manner. An intervention was considered to be efficiently delivered if it could be delivered in one or more of the following methods: in a group, delivered by assistants-volunteers, or delivered by technology (computer, telehealth);
4. Interventions that had been delivered at a frequency and intensity of at least five hours a week were considered intensively delivered (77);
5. Interventions were considered to be targeting conversation if the underlying mechanism of action or theoretical underpinning was reported as targeting conversation, functional communication or communicative competence;
6. As the interventions were aimed at improving conversation the outcome of interest was functional communication and in order to fully assess effective interventions, change on all domains of the International Classification of Disability and Functioning (ICF) were of interest: change in impairment, change in activity and change in participation. Change in quality of life was also of interest.

2.2 Methods

Several systematic reviews of aphasia interventions have been completed including a Cochrane review (28). Therefore, an overview of systematic reviews was completed in order to meet the research objectives. This method was designed to compile evidence from multiple systematic reviews and combine them into a single source which allowed the synthesis of outcomes from the breadth of literature on aphasia interventions (78). This review was conducted in accordance with the Cochrane handbook of systematic reviews and followed the PRISMA statement. The protocol was not registered on PROPSPERO.

2.2.1 Search strategy

A systematic search strategy was used to ensure a comprehensive search of all available reviews was completed. The search terms included “stroke”, “aphasia”, “rehabilitation” and “review/meta-analysis”, as well as related concepts and synonyms (Appendix 1 Search Strategy full terms). Cochrane and non-Cochrane reviews were included to ensure the breadth of the aphasia intervention literature was explored in this review. Cochrane systematic reviews include only RCT evidence from the literature and much of the aphasia research includes case series and case study evidence. Consequently, excluding non-Cochrane reviews risks overlooking interventions for aphasia that have not yet been studied in a RCT design. The difficulty in including non-Cochrane reviews in the overview was that there may be overlap in the included primary research studies and participants and outcomes may be double counted. Therefore, redundancy testing was completed in two stages to combat the risk of double counting. See section 2.3.5 Redundancy testing for methods. Four databases were selected that reflect the diverse range of disciplines involved in the research of aphasia; Cochrane database, Medline (Ovid), CINHL (EBSCO) and PsycINFO (APA PsycNET). An information specialist within the School of Health and Related Research was consulted in the development of this search strategy. The search was conducted in July 2016 and updated in April 2020. A search was also conducted to determine if any new RCT’s had been reported since July 2016 that had not yet been included in systematic reviews for interventions that improve conversation through the remediation of spoken language impairment caused by aphasia, and have been delivered intensively and efficiently (see section 2.2.8 Analysis of interventions identified in the reviews for definition of intensively and efficiently). The updated data from July 2016 onwards is presented in section 2.4 Update of overview at the end of this chapter.

2.2.2 Study Selection

Two independent reviewers screened all titles and abstracts generated by the search strategy. The lead reviewer was the research SLT (PhD candidate) and the second reviewer was a clinical SLT working in the NHS. A validated electronic screening tool (Covidence Systematic Review Software, Veritas Health Innovation, Melbourne, Australia Available from: www.covidence.org) was used for screening titles and abstracts. All records identified by the database searches were uploaded into the screening tool to identify and remove duplicates. Abstracts were categorised as either ‘include’, ‘exclude’ or ‘unsure’ based on the eligibility criteria (section 2.2.3 Eligibility Criteria). Full text articles of all reviews categorised as ‘unsure’ were reviewed by both reviewers. All disagreements were resolved by consensus and relevant articles were categorised as included. All full text articles of the abstracts that were categorised as ‘included’ were then screened against the eligibility criteria by the lead reviewer only.

2.2.3 Eligibility Criteria

The following criteria were used for inclusion and exclusion in this review:

1. The review relates to aphasia caused by stroke
2. The review is a review of literature
3. The review is published in English
4. The review includes studies of adults (18 years+)
5. The review includes evaluations of interventions using any design (e.g. Randomised control trial, cohort study, case-series, case study etc.)

Non-Cochrane systematic reviews were included if the methods detailed a systematic search of the literature. Those studies that assessed only the most recent research or summarised the research to describe a method, principle or theory were excluded.

All interventions that aimed to remediate an element of aphasia including interventions intended to impact reading, writing, spoken language and understanding language were included to ensure the breadth of aphasia interventions were identified. Adjunct interventions such as prescription of medications and transcortical stimulation were not included if delivered alone however if behavioural interventions and adjunct interventions were delivered together these studies were included in this review.

2.2.4 Data extraction

Data extraction was a three-part process. Firstly, data from each review was extracted including: the area of aphasia studied, how many studies were included, the number of participants included, whether a meta-analysis was conducted and for outcomes and recommendations regarding: frequency and intensity of aphasia therapy delivery; mode of delivery; non-professionals involved in aphasia therapy delivery; and, efficacy of interventions.

Secondly, all aspects of the AMSTAR 2 (A MeaSurement Tool to Assess Systematic Reviews (79))were extracted to assess the quality of included reviews.

Thirdly, interventions examined by the systematic reviews were identified. Interventions were also extracted from the ongoing, awaiting results and excluded reference lists of the Cochrane review to ensure no intervention was excluded at this stage. The following data was extracted for these interventions: whether the intervention targeted conversation; had an impairment focus; and, was delivered face-to-face, in a group or by non-professionals.

2.2.5 Redundancy testing

A two stage redundancy testing process was completed. Firstly, all included systematic reviews which examined Randomised Control Trials (RCT) were cross referenced with Brady et al., (2016) (28) Cochrane review to identify overlap in primary research studies and determined the level of redundancy between Cochrane and non-Cochrane reviews which allowed any overlapping RCT outcome data to be identified and avoid any double counting in line with the decision-making tool devised by Pollock and colleagues (80).

Secondly all interventions identified in non-Cochrane reviews were cross referenced with Brady et al., (2016) Cochrane review (28) to ensure that all interventions were included no matter the trial design.

2.2.6 Synthesis of findings

The conclusions of each review were reported in Table 3 and a summary of these conclusions was presented. A meta-analysis was planned with the review data that remained after redundancy testing. Interventions identified through the reviews and ongoing trials lists were compiled and categorised according to the underlying principle on which they were developed (see Table 5).

2.2.7 Quality assessment

The quality of the included reviews and the quality of the evidence for included interventions was examined using the following methods.

2.2.7.1 Quality of the included reviews

Each included review was assessed for quality using the AMSTAR tool. Each review's AMSTAR items were summarised by an overall confidence rating using the following scale:

- High: no or one non-critical weakness
- Moderate: more than one non-critical weakness
- Low: one critical flaw with or without non-critical weaknesses
- Critically Low; more than one critical flaw with or without non-critical weaknesses

The AMSTAR domains considered critical were:

- Protocol registration prior to commencement of review,
- Adequate literature search strategy,
- Justification of excluded systematic reviews,
- Assessment of the risk of bias in included systematic reviews,
- Appropriate meta-analytical methods,

- Risk of bias considered when interpreting results,
- Assessment of presence and likely impact of publication bias.

This quality assessment of included reviews was important to determine the risk of bias and therefore the confidence placed in the evidence presented in each review.

2.2.7.2 Quality of evidence for interventions identified in the reviews

The GRADE (Grading of Recommendation, Assessment, Development and Evaluations) approach was used to assess the confidence in the outcomes. The GRADE approach was chosen as it allows a clear judgment about confidence in effect estimates and weights the importance of different outcomes thus providing a pragmatic interpretation of the strength of the recommendation.

The GRADE assessment used the following steps:

1. The Population Intervention Comparator Outcome (PICO) was used to define the question
    1. The population was defined as adults aged over 18 years of age with a diagnosis of aphasia as a consequence of stroke
    2. Interventions were identified from the reviews and assessed for evidence that they were targeting communication impairment, intensively and efficiently delivered.
    3. Any other intervention for aphasia was included as the comparator
    4. As stated in section 2.1 functional communication was the key outcome through the full range of the ICF domains and including quality of life.

- Each intervention was tested using the following question; Was [potential aphasia intervention] vs [any other aphasia intervention] effective for treating aphasia as a consequence of stroke?

1. Each potential intervention was assessed to identify the:
    - list of outcomes;
    - number of participants and studies;
    - relative effect (95% CI);
    - direction of the effect; and,
    - a rating of the overall quality of the evidence.

2.2.8 Analysis of interventions identified in the reviews

The following questions were then asked of each intervention identified from the reviews to meet the objectives of this review:

- Does this intervention improve conversation?;
- Does this intervention remediate spoken language impairments caused by aphasia?;
- Has this intervention been delivered intensively?
- Has this intervention been delivered efficiently?; and,

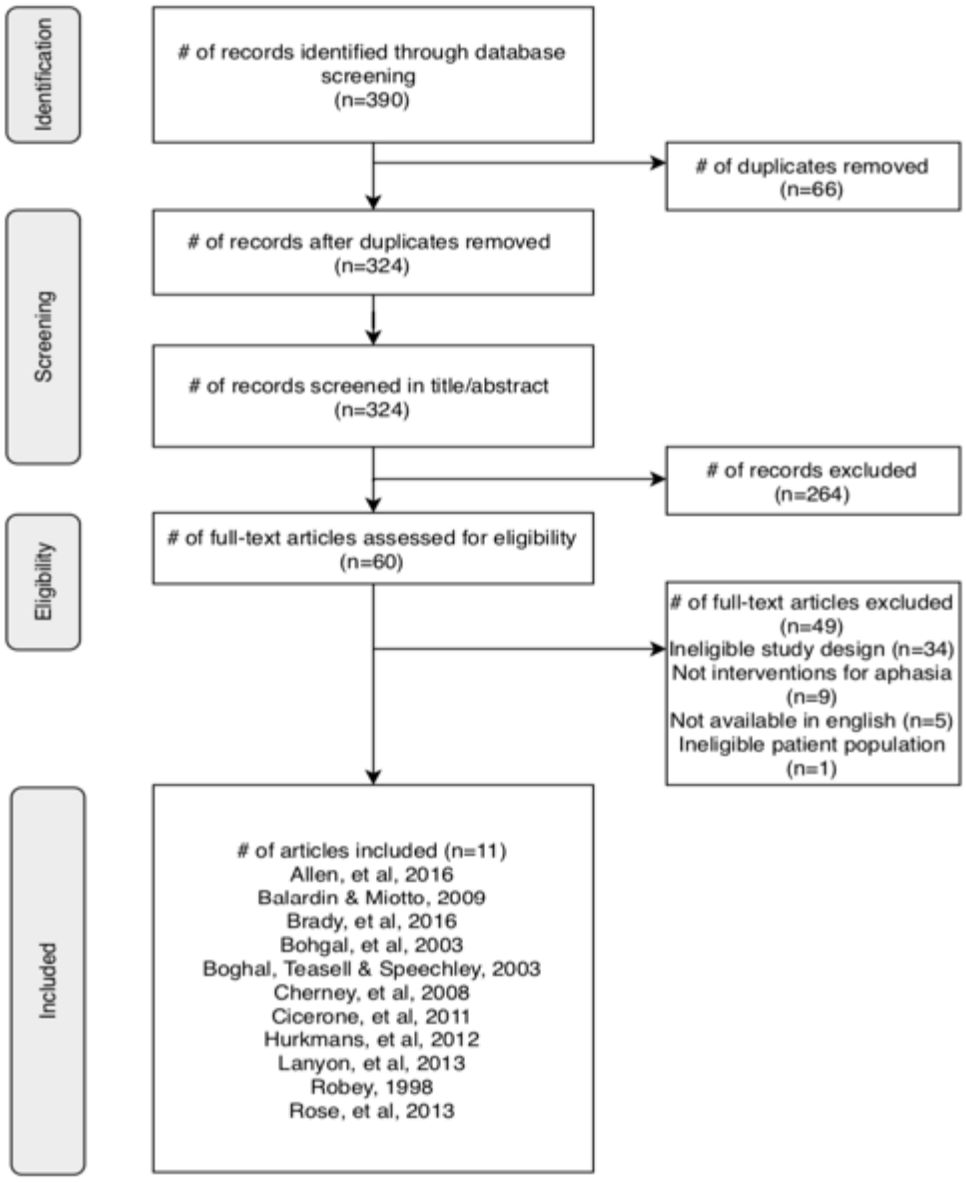
- What is the level of evidence for the intervention?

2.3 Results

2.3.1 Included Systematic Reviews

Figure 5 shows the study flow PRISMA diagram(81). After eliminating duplicates 390 unique systematic reviews were identified. 264 reviews were excluded at title/abstract stage as study design, population or intervention was ineligible. 60 full text systematic reviews were appraised and 49 were excluded for reasons of ineligible study design, (non-systematic review or opinion paper n=34), not being available in English (n=5) not assessing interventions for aphasia (n=9), or ineligible patient population (n=1). This resulted in 11 reviews being included in this overview. See the list of excluded reviews in Appendix 2.

Figure 5 Study Flow (PRISMA) diagram



2.3.2 Study characteristics

Table 3 shows the included systematic review characteristics. Eleven systematic reviews were extracted with dates ranging from 1998 to 2016. In total, the eleven systematic reviews encompassed 229 primary studies which included 6309 participants. However, significant overlap of primary research studies between systematic reviews was observed and will be further discussed in section 2.3.4 Results of Redundancy testing. Primary research study designs included Randomised Controlled Trials, non-randomised group studies, quasi-experimental studies, cohort studies, case series, single case studies/descriptions and expert opinion.

2.3.2.1 Areas of aphasia assessed by included studies

Four systematic reviews assessed the effectiveness of aphasia interventions (28,82–84) with one review specifically focused on the effectiveness of early aphasia interventions delivered 6 months' post stroke. Three systematic reviews examined the intensity of aphasia intervention delivery (14,75,85). Five systematic reviews assessed the effectiveness of a specific intervention for aphasia. Of these five systematic reviews, three examined the effectiveness of Constraint Induced Aphasia Therapy (14,85,86). The remaining two assessed the effectiveness of music therapy (87) and gesture therapy (88). A further two systematic reviews examined the mode of delivery of interventions for aphasia including, group therapies (14,89) and volunteers vs. professional delivered interventions (14).

2.3.2.2 Data synthesis in included reviews

Table 3 summarises the conclusions of data synthesis within included systematic reviews. Five reviews presented no statistical meta-analysis at all (14,82,83,86,87). Four systematic reviews conducted meta-analysis of the included studies, however, four of these systematic reviews reported effect sizes for individual outcomes rather than synthesised results (84,85,88,89). Two reviews reported Standardised Mean Differences (28,75).

2.3.2.3 Reported conclusions of the reviews

Each systematic review shown in Table 3 reported conclusions in statements of effect specific to the area of aphasia assessed which were reported in Table 3. Effects were reported with varying degrees of certainty with one study reporting the interventions assessed were effective (82) whilst all other reviews were more cautious in reporting the results (see Table 3). Two reviews reported on the effectiveness of computer mediated interventions for aphasia: Brady, et al. 2016 reported no evidence of benefit or harm (28), and Allen et al. 2012 reported it was effective (82). Two reviews reported on the effectiveness of volunteer delivered SLT compared to professional delivered SLT; Brady et al. (2016) reported there was no evidence of benefit or harm (28) and Bhogal et al. (2003),

reported there was strong evidence that volunteers can provide equivalent therapy to professional speech and language therapists (14). Three reviews reported on group interventions for aphasia: Allen, et al. (2012) reported group therapies are effective (82), Brady, et al. (2016) reported there is no evidence of benefit or harm and Lanyon et al. 2003 reported evidence favours highly structured groups (89). Four reviews reported on comparisons between one type of intervention and another and all reported that there was no evidence to support one intervention over another (28,84,85). Seven reviews reported the importance of intensity and massed practice. Robey, 1998 reported an intensity more than two hours a week may be beneficial (84). The remaining six reviews reported more broadly that intensively delivered interventions caused improved outcomes for people with aphasia (14,28,82,83,85,86). Several reviews reported on the effectiveness of specific interventions (gesture, music therapy, CIAT). One review reported insufficient evidence for music therapy (87). One review reported further evidence is needed for gesture based and combined gesture and spoken language interventions (88). Five reviews reported evidence for Constraint Induced Aphasia Therapy (CIAT) ranging from premature to conclude there is any advantage to constraint methods (85,86) and no evidence of benefit or harm (28), to moderate evidence of effect (14) and the statement that CIAT is effective (82).

2.3.3 Quality of systematic review evidence

Results of AMSTAR ratings can be found in Table 4. AMSTAR rating revealed one high quality Cochrane review (28), one moderate quality review (89), one low quality review (85) and eight critically low quality reviews (14,75,82–84,86–88). Poorly assessed and discussed risk of bias was a common critical flaw. Only the Cochrane review (28) provided a list of the excluded studies, whilst all other reviews provided variable justification for exclusion of studies but did not list those studies that were excluded. Nine systematic reviews failed to assess or discuss publication bias, (14,75,83–89). Seven reviews did not declare any conflict of interest (14,75,83,84,86–88). Due to the critically low and low quality of the included systematic reviews little confidence can be placed in the findings being unbiased, except in the case of the high quality Cochrane review (28).

Table 3 Study Characteristics and conclusions of data synthesised in each review

Study	Areas of Aphasia assessed	Meta-analysis conducted	No. of studies included	n	Study designs	Review Conclusions
1 Allen et al. 2012(82)	Effectiveness of interventions 6 months' post stroke	No	21	499	RCT	• Computer based techniques effective • CIAT effective • Intensive aphasia therapy effective • Group therapies effective • Conversation partner training effective 1. Community based programs effective
2 Balardin & Miotto, 2009 (86)	Constraint Induced Aphasia Therapy	No	5	76	2 RCT 2 NRSI 1 Case series	• Premature to conclude any advantage of constraint methods • Intensity may be beneficial 2. Results may not be maintained
3 Brady et al. 2016(28)	Effectiveness of Aphasia interventions	Yes	27	1620	RCT	3. Functional SLT vs no SLT favours SLT 4. Receptive Language - comprehension no evidence of benefit or harm 5. Receptive language – reading favours SLT 6. Naming no evidence of benefit or harm 7. Expressive language – general favours SLT 8. Expressive language – written Favours SLT 9. Number of dropouts no evidence of benefit or harm 10. High intensity vs low intensity favours high intensity 11. Group therapy no evidence of benefit or harm 12. CIAT no evidence of benefit or harm 13. Volunteer no evidence of benefit or harm 14. No evidence to support one therapy over another
4 Bhogal, et al. 2003(14)	Intensity of Aphasia therapy	No	8	986	RCT Cohort Case studies Consensus	• Strong evidence intensive therapy with massed dose can improve language
	CIAT		Not available	Not available		• Moderate evidence that CIAT results in improved language
	Volunteers vs trained professionals		5	488		• There was strong evidence that volunteers can provide equivalent therapy to that of trained SLT
	Group Therapy		2	54		• There was limited evidence that group aphasia therapy can improve language

5 Bhogal, Teasell & Speechley, 2003(75)	Intensity of Aphasia Therapy	Yes	10	864	RCT	• Our review confirms that lower-intensity therapy provided over a longer period does not result in a significant change in outcome. However, more intensive SLT, delivered over a shorter period, results in significant improvement in outcome. We conclude that intensive aphasia therapy delivered over 2 to 3 months was critical to maximizing aphasia recovery.
6 Cherney et al. 2008(85)	Intensity of aphasia therapy CIAT	ES reported	10	141	Controlled trial Case study Cohort Study Expert consensus	• Regardless of type of treatment, more treatment was better over a restricted time interval • Clear and convincing evidence of CIAT effectiveness over other aphasia interventions has not yet been established
7 Cicerone, et al. 2011(83)	Effectiveness of Aphasia therapy	No	37	Not reported	RCT Cohort Case Study	• There was a continued need to investigate language treatment (timing, dosage) that contribute to therapy effectiveness. Although therapy intensity should be considered as a factor.
8 Hurkmans, et al. 2012(87)	Music therapy for aphasia	No	15	583	Group studies Case series Case studies	• Measurable improvement was reported in studies where musical components were used in the treatment of neurological language and speech disorders. However, the methodological quality of studies was rated low. Therefore, no conclusions can yet be drawn regarding the effect of the use of musical elements in the treatment of individuals with acquired neurological disorders.
9 Lanyon et al. 2013(89)	Effectiveness of Group Aphasia Therapy	ES Reported	11(28)	Not reported	RCT NRCT Single case design Case series	• The evidence favours participation in community and outpatient groups that use highly structured protocols. There is also modest evidence that aphasia groups using multi-modality communication activities can improve social networks
10 Robey et al. 1998(84)	Effectiveness of Aphasia therapy	ES reported	55	864	Quasi-experimental	• Treatment for aphasia is effective, treatment greater than 2 hours a week has better results, • No comparison between effects of different treatments and type of aphasia can be made. • Gains can be achieved in chronic aphasia and in severe aphasia

11 Rose, et al. 2013(88)	Gesture therapies and aphasia	ES reported	23	134	Group studies Case studies	• there is reasonable evidence from high-quality SCEDs that combined symbolic gesture + verbal training has a positive impact on trained items for language impairment measures such as picture naming for both nouns and verbs. • combined training can be superior for some participants with aphasia, particularly for maintenance of verbal language gains • effects for untrained words were typically limited • questions concerning the impacts of gesture treatments for people with fluent aphasia relatively unanswered.

ES=Effect Size RCT=Randomised Control Trial CIAT = Constraint Induced Aphasia Therapy SCED = Single Case Experimental Design

Table 4 AMSTAR Quality Assessment table

AMSTAR Items	Allen, et al. 2012	Balerdin & Miotto, 2009	Bohgal , et al. 2003	Bohgal, Teasell &Speechley, 2003	Brady, et al. 2016	Cherney, et al. 2008	Cicerone, et al. 2011	Hurkams, et al. 2012	Lanyon, et al. 2013	Robey, 1998	Rose, et al. 2013
1. Components of PICO provided?	+	+	+	+	+	+	-	+	+	+	+
2. Explicit report of review methods?	-	-	-	-	+	+	-	+	+	+	+
3. Study design selection justified?	-	+	-	-	+	+	+	-	-	+	+
4. 3. Was a comprehensive literature search performed?	0	-	-	-	+	+	-	+	+	+	+
5. Was there duplicate study selection?	-	-	-	+	+	+	+	+	+	-	+
6. Was there duplicate data extraction?	-	+	-	+	+	+	-	-	-	-	+
7. Listed and justification of excluded studies?	-	-	-	-	+	-	-	-	-	-	-
8. Were the characteristics of the included studies provided?	+	0	0	-	+	+	-	+	+	+	+
9. Risk of bias assessment completed?	+	+	-	-	+	+	-	+	+	+	+
10. Sources of funding reported?	-	-	-	-	+	-	-	-	-	-	-
11. Were the methods used to combine the findings of studies appropriate?	N/A	N/A	N/A	-	+	-	N/A	N/A	+	+	+
12. Impact of the Risk of bias considered in the evidence synthesis?	N/A	N/A	N/A	-	+	-	N/A	N/A	+	-	+
13. Risk of bias considered in the interpretation and discussion of evidence synthesis?	+	-	-	-	+	+	-	-	+	-	+
14. Satisfactory explanation of heterogeneity?	+	+	-	-	+	+	-	-	+	+	-
15. Was the likelihood of publication bias assessed and discussed?	+	-	-	-	+	-	-	-	-	-	-
16. Any conflict of interest reported?	+	-	-	-	+	+	-	-	+	-	-
Rating overall	CL	CL	CL	CL	High	Low	CL	CL	Mod	CL	CL

Mod= Moderate N/A= Not applicable 0= partial yes CL= Critically Low

2.3.4 Results of Redundancy testing

2.3.4.1 Redundancy testing of RCTs

Before reporting on studies of specific interventions, it is necessary to report any overlap between the reviews. Appendix 3 shows the results of RCT's extracted from the systematic reviews were cross-referenced to the Cochrane review (28) which determined the level of redundancy in the results and ensured no RCT results were omitted from this review. Four RCT's were identified that were not included in the Cochrane review (28). Two RCT's (90,91) were quasi-randomised trials, one RCT did not have a randomized design (92) and one RCT had inadequate allocation blinding that allowed treatment group to be predicted (93).

2.3.4.2 Redundancy testing of aphasia interventions

Appendix 4 shows a list of identified interventions from included systematic reviews that were assessed in randomised or non-randomised trials. No interventions identified in the non-Cochrane reviews were excluded from the Cochrane review (28). One intervention, Multi-Modal Aphasia Therapy (58) was identified, in the trials in progress list of the Cochrane review, which had not yet been assessed in a randomised control trial. Multi-Modal Aphasia Therapy was identified through the ongoing trials listed in the Cochrane review (28). All other interventions identified were included in the Cochrane review as at least one RCT design has been reported for all interventions (28). This demonstrated that all interventions for aphasia were identified by the Cochrane review and that the list of interventions included in this review was comprehensive.

2.3.5 Synthesis of findings

The Brady et al. (2016) Cochrane review investigating the effectiveness of aphasia interventions contained all the quality randomised controlled trial data from all those systematic reviews included in this review. Therefore, in-line with Pollock et al. (2019) (80), decision making tool and due to the comprehensive nature of Brady et al (2016) (28) and the low quality of the included reviews a further meta-analysis of this data was not required. The objective of this review was to identify interventions for aphasia using a systematic and comprehensive search strategy and section 2.3.6 outlines the interventions found and their applicability to the criteria; improve conversation by targeting spoken language and have been delivered intensively and efficiently and review the evidence for those interventions identified.

2.3.6 Identified interventions for aphasia

Table 5 shows the interventions identified through the review, and the results of the first four questions asked of each intervention for aphasia described in the systematic reviews about whether

it: 1) targeted conversation, 2) was impairment based, 3) was intensely delivered and 4) had used an efficient mode of delivery (see section 2.2.8 Analysis of interventions identified in the reviews).

Table 5 Interventions for Aphasia

Category	Example Interventions	Targets Conversation	Impairment based	Intensively Delivered	Mode of delivery	
					Group	Delivered by non-professionals
Language models	Semantic Semantic Feature Analysis(50), BOX(51) Semantic complexity training, contextual priming , semantic judgments	-	+	+	-	+
	Phonological Word retrieval strategies (phonemic), phonemic judgements	-	+	+	-	+
Language domains/skills	Naming therapy word retrieval strategies (semantic/phonemic), word to picture matching	-	+	-	-	-
	Reading therapy(94) ORLA(95), supported reading comprehension	-	+	+	-	-
	Writing therapy (96)	-	+	+	-	-
	Verb treatments (97)	-	+	+	-	-
	Syntax/grammar therapy Preposition therapy, sentence production program for aphasia, treatment of underlying forms Syntax training(98)	-	+	-	-	-
	Comprehension therapies, Sentence Mapping Intervention	-	+	+	-	-
	Narrative Interventions NARNIA, picture description	-	+	+	-	-
	Gestural therapies, Visual Action Therapy	-	+	-	-	-
Compensatory	Compensatory training, total communication, Life participation Approach to Aphasia	-	-	+	+	-
	Alternative and Augmentative Communication (99)	-	-	-	-	-
Functional	Script training (100)	-	+	+	-	-
	Key Word Training	+	-	-	+	+
Social	Conversation Partner Training (101) Conversational coaching (102)	+	-	-	+	+
	Supported conversation (101)	+	-	-	+	-
	Support and Social Stimulation	-	-	+	+	+
	Psychological and emotional support(103)	-	-	-	+	-
Computer based therapies	Step by Step(104), REACT(105), Aphasia therapy online(106)	-	+	+	-	+
Intervention packages	Melodic Intonation Therapy(107) SIPARI	-	+	+	-	+
	Cognitive Linguistic Therapy (108)	-	+	+	-	-
	Constraint Induced Aphasia Therapy/Intensive Language Action Therapy(57)	+	+	+	+	+

	Multimodality Aphasia therapy (58)	+	+	+	+	-
	Promoting Aphasic Communicative Effectiveness(109)	+	-	+	+	-
	Reciprocal scaffolding(110)	-	-	+	+	-
	Response Elaboration Training (111)	+	+		-	-

2.3.6.1 Interventions

Seven categories of interventions for aphasia were identified:

1) models of language production; which included semantic interventions such as Semantic Feature analysis and phonological interventions such as word retrieval strategies;
2) language domains or skills such as reading, writing, syntax/grammar, comprehension, narrative and gestural therapies;
3) compensatory interventions; that aim to support the person with aphasias communication rather than remediate the aphasia as well as augmentative and alternative communication that again supports the person with aphasia to communicate by supplementing spoken communication with other forms of communication e.g. writing, gesture, pictures or devise use;
4) functional communication; such as key word training of supported conversations where the person with aphasia attempts to learn phrases or words that will support communication,
5) social support; where the focus of the intervention is not on remediating aphasia but providing a supportive conversation partner or communicative environment;
6) computer delivered interventions; that are supported by technology, these interventions target different language domains such as naming, language comprehension or reading; and,
7) intervention packages; that have a clearly defined treatment protocol and have underlying principles that overlap between categories of interventions.

Within these seven categories 25 types of intervention for aphasia were identified from the reviews. 17 of these intervention types represent a category of many individual procedures using a single underlying principle or aphasia treatment. For example, phonological therapies are delivered following many different protocols but fundamentally aim to target the phonological or sound systems within the neural networks; writing interventions target writing; alternative and augmentative interventions train people with aphasia to use systems other than spoken language to communicate and so on. The remaining seven interventions in Table 5 are specific manualised interventions that are designed to be delivered in a consistent way following a set procedure (Melodic Intonation Therapy (107), Constraint Induced Aphasia Therapy/Intensive Language Action Therapy (CIAT/ILAT(57)), Multi-modality Aphasia Therapy (M-MAT(58)), Promoting Aphasic Communicative Effectiveness (PACE(109)), and Reciprocal Scaffolding (110), Response Elaboration Training).

2.3.6.2 Targeting conversation

Six of the interventions purport to target communication at the level of conversation (CIAT (57), M-MAT (58), PACE (109), Response Elaboration Training, Reciprocal Scaffolding (110), Conversation Partner Training and Supported conversation (101)). The remaining types of interventions have a

varied focus ranging from targeting single words or improving sentence structure (98), reading (94), writing, teaching compensatory strategies, using alternative or augmentative communicative systems or devices (99) and, the psychological well-being of people with aphasia (103).

2.4.6.2 Impairment based interventions

Fifteen of the included interventions were impairment based interventions which were defined as those interventions that aimed to remediate aphasia through directly improving the impairment caused by aphasia (body structure and function level of the ICF (34)). Of these interventions two also targeted conversation Constraint Induced Aphasia Therapy (CIAT) also known as Intensive Language Action Therapy (ILAT) and Multi-Modality Aphasia Therapy (M-MAT). CIAT/ILAT attempts to remediate aphasia through Language Action Games played in a behaviourally relevant context of a group using barriers and stimulus cards to request items and plan activities with co-players. Rules are set for each individual to focus on spoken communication to be the most complex and accurate that the individual is capable of achieving; then spoken output is incrementally shaped to more complex and accurate spoken communication as therapy progresses (57). M-MAT also aims to remediate aphasia through games played in a behaviourally relevant group context. No barriers are used and cueing and prompting are provided through all means of communication: writing, gesture, drawing, as well as verbally. People with aphasia communicate through any means: verbally, writing, gesture, drawing or any combination of these means. Responses are also shaped in a similar way to CIAT (58).

Eight of the included interventions were compensatory or socially based rather than impairment-based interventions. Of these three interventions (supported conversation, reciprocal scaffolding and PACE) also target conversation. Conversation partner and supported conversation training target conversation through focusing on managing aphasia within the conversation, putting the onus on the partner to use strategies to compensate for the aphasia rather than attempting to remediate the impairment caused by the aphasia (101). PACE also does not attempt to remediate the conversation impairment, instead the goal is to practise techniques modelled by the therapist and convey a message by any means (109). The originators of PACE assert that no attempt is made to prompt or correct the person with aphasia. Furthermore, the person with aphasias turn ends when the message is understood without requiring any specific spoken output to be produced. Therefore, if the communication partner manages to decipher the message from the person with aphasia this is considered a successful exchange. In this way, there is a heavy reliance on the message receiver to decode the message rather than the person with aphasia to improve the message (109).

2.3.6.3 Intensively delivered interventions

As defined in section 2.2.8 Analysis of interventions identified in the reviews, intensively delivered interventions were those delivered for at least five hours a week (77). Aphasia interventions were classified as being delivered intensively if reports in the literature stated a frequency of more than five hours a week. Table 5 indicates those interventions that have reports in the literature of intensive delivery. PACE, Multimodal therapy and CIAT/ILAT have all been reported at schedules of 30 hours of therapy across ten working days (58,112–114). Computer based therapy, semantic feature analysis and phonological therapies have been delivered on varying treatment schedules up to and including 16 hours over three weeks (115). Reading therapy was reported to be delivered for four to five hours a day over a period of several months both through independent work with a computer, a speech therapist and a volunteer (116). Gestural interventions have been delivered on varying intensities including an intensive schedule of one hour a day five days a week for two weeks (117). Compensatory training and total communication within functional activities were delivered for 20 hours weekly for five weeks (118). Melodic Intonation Therapy was delivered for eight to ten hours per week for 12 weeks (119). Verb therapies were delivered at intensive and non-intensive rates, Mattioli and colleagues (120) delivered a verb therapy for one hour a day five days a week for two weeks. Reading and writing therapies were also delivered weeks at an intensity of ten hours weekly for six weeks (121). Reciprocal scaffolding, response elaboration training and supported conversation, conversational coaching, support and social stimulation, psychological and emotional support, syntax therapies and narrative interventions have not been reported at intensities of at least five hours a week.

2.3.6.3 Mode of delivery

Table 5 shows the mode of delivery for each intervention. The mode of delivery was examined to determine which of the interventions had been delivered in an efficient manner. Nine of the intervention types had been delivered in groups (CIAT/ILAT, Multimodality stimulation therapy , PACE, Conversation Partner training, Compensatory training, Supported conversation, Support and Social Stimulation, Psychological and emotional support, Functional communication). Ten interventions had been delivered by non-professionals Semantic, Phonological, Melodic Intonation therapy CIAT/ILAT, PACE, Conversation Partner training, Support and Social Stimulation and computer mediated interventions). Types of non-professionals included volunteers and family members.

Figure 6 Results of intervention selection

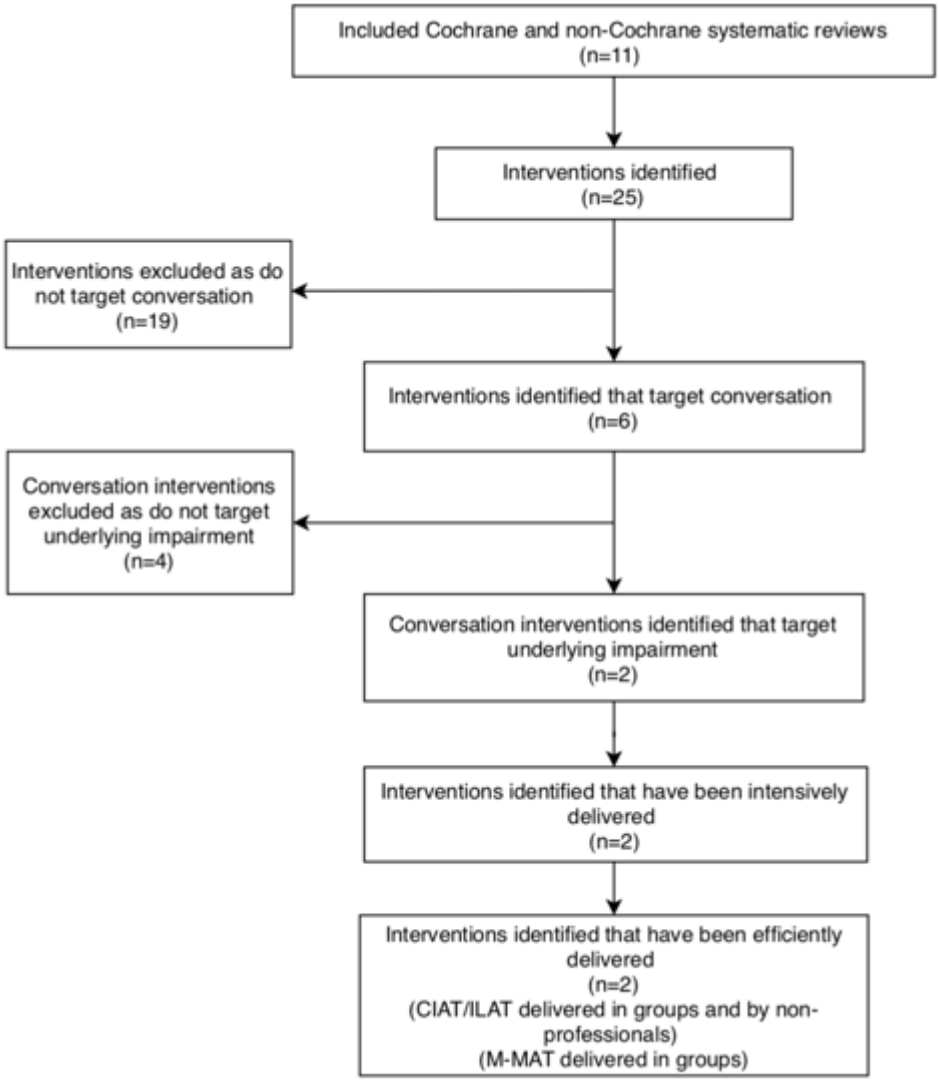
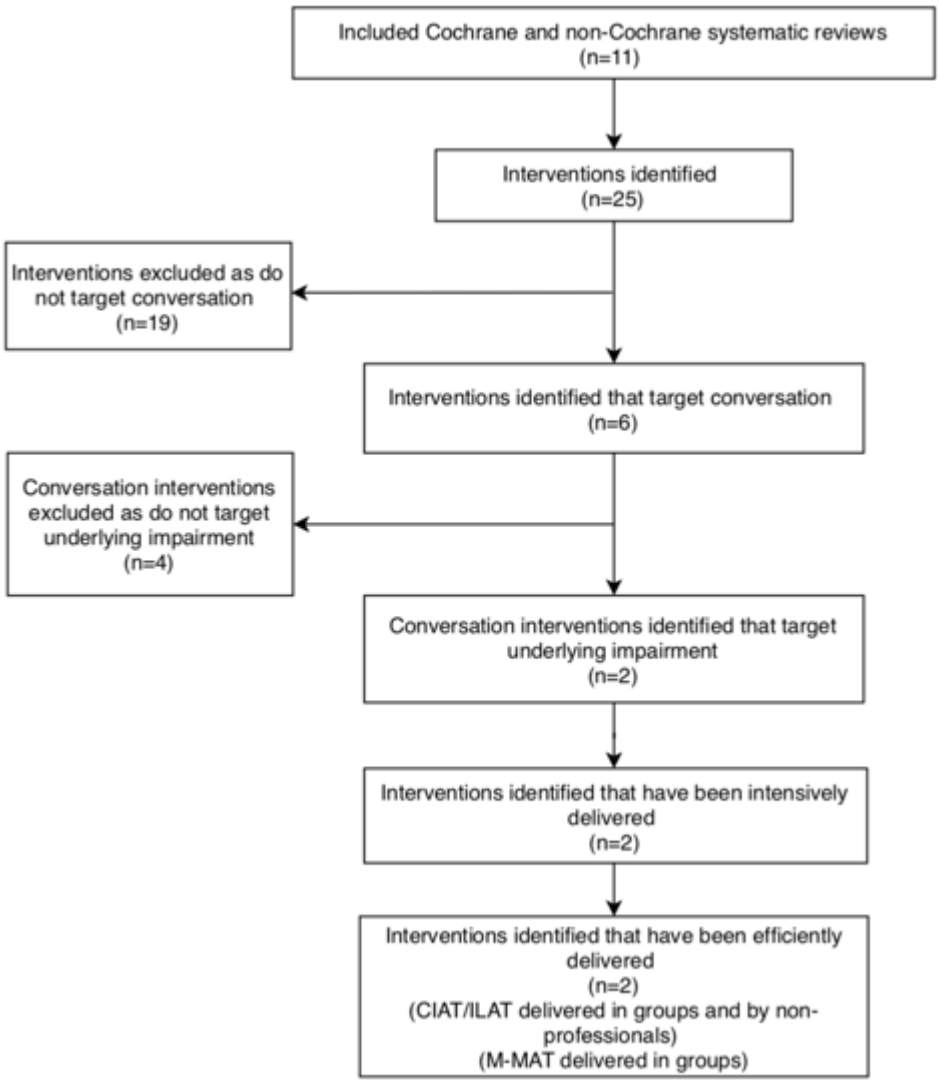


Figure 6 shows the results of interventions assessed against the criteria of: targets conversation through spoken language, delivered intensively and delivered efficiently. Of the 25 types of interventions included six target conversation, of those six, two have an impairment based approach. CIAT/ILAT and M-MAT have both been delivered intensively and in a group. However, only CIAT/ILAT has been delivered by non-professionals (122).

Figure 6 Results of intervention selection



2.3.7 Results of GRADE assessment for identified interventions for aphasia

All interventions meeting the criteria of targeting conversation through remediating spoken language impairment, intensively and efficiently delivered were considered for assessment of quality using GRADE. Consequently CIAT/ILAT and M-MAT were considered. Unfortunately, there are no published RCTs of M-MAT to assess within GRADE thus M-MAT had very low quality evidence due to the existing designs of completed studies and the uncertainty of the results without a control group. A GRADE assessment had been completed by the 2016 Cochrane review for CIAT/ILAT compared to other Speech and Language Therapy (SLT) interventions. As no new RCTs examining CIAT/ILAT have been identified to include in an updated GRADE assessment the results from the Cochrane review are displayed in Appendix 5. Functional communication was the outcome assessed in a comparison between CIAT and any other intervention for aphasia. 126 participants were included across three RCTs. A Standard Mean Difference (SMD) of 0.15 (95% CI -0.21-0.50) was found with the direction of effect being uncertain. The quality of the evidence was low. Despite this low rating, as M-MAT had

not yet been assessed in RCT design, CIAT/ILAT was selected as an appropriate intervention with the best available evidence for further examination in the NHS.

2.4 Update of overview

The original searches for this overview were completed in 2016 after which further research of CIAT/ILAT commenced. However, it was important to search the literature again and update this review to determine if any other interventions have been reported in the past four years from 2016 to 2020. Therefore, the search was repeated as described in section 2.2.1 Search strategy. Four new systematic reviews were identified. However it was not possible to obtain the full text version of one review published in 2020 that was examining the effects of distributed practice on naming therapy (123). The failure to obtain this review was due to restricted library services, attempts were made up until June 2020 without success. Therefore three systematic reviews were assessed.

2.4.1 Study Characteristics

Table 6 summarises the systematic review characteristics. One review examined treatments for aphasia using technology (124), one review examined conversation partner training (125) and one review examined Constraint Induced Aphasia Therapy/ILAT (126). Two reviews included meta-analysis (124,126). The three systematic reviews included 56 primary research studies representing 750 participants. Zhang et al. 2017 only included primary research from RCTs (126) whilst the remaining two reviews also included single case studies and non-randomised trials (125,127) Simmons-Mackie et al. (2016) included qualitative data (125). Two of the reviews, although reporting on different areas of aphasia treatment, found that massed and intensive interventions schedules may be beneficial (126,127).

2.4.2 Quality of the reviews

Table 7 summarises the quality of the new reviews. AMSTAR rating revealed that all three reviews failed to justify or list the excluded reviews, sources of funding were not reported and risk of bias in the synthesis of the results was not considered or discussed resulting in one low quality (124) and two critically low quality reviews (125,126).

2.4.3 Interventions identified

No new interventions were identified in the three new included reviews.

A search of the research from 2016 to March 2020 was completed to determine if any new interventions that fit the criteria for consideration for this study had been reported since the initial

search in 2016 that might not have been reported in the systematic reviews. The criteria were interventions that target conversation, through remediating spoken language, that had been delivered efficiently. The same search strategy as that used for the overview up until limiting the search to reviews was used (see Appendix 1 up to and including step five). Four databases were selected that reflect the diverse range of disciplines involved in the research of aphasia; Cochrane database, Medline (Ovid), CINHL (EBSCO) and PsycINFO (APA PsycNET). This strategy identified interventions for aphasia caused by stroke reported since 2016. 34 research studies were identified. 30 research studies were excluded in screening title and abstract as the study design, population or intervention were ineligible. Four articles were assessed using the criteria: targeting conversation, remediating spoken language and had been delivered efficiently. All four were excluded; one as it was an ineligible study design (128), and three because of ineligible intervention as none targeted conversation (129–131). Therefore, no new interventions were identified.

Table 6 Study characteristics

Study	Areas of Aphasia assessed	Meta-analysis conducted	No. of studies included	n	Study designs	Outcomes
Lavoie, Macoir & Bier, 2017	Technology and aphasia	Magnitude of change reported	23	170	RCT Single subject studies	• Technology is an efficient approach to the management of post-stroke anomia. • More studies are needed to confirm these results • Intensive treatment (more than 2x/week) and a high number of treated items seem to be associated with better treatment outcomes. • It is not possible to confirm that self-administered therapy is as effective as traditional face-to-face therapy.
Simmons-Mackie et al. 2016	Conversation Partner training	No	25	308	RCT NRCT Single case design Qualitative studies	• Insufficient evidence is available for the effectiveness of partner training in people with acute aphasia • Inadequate evidence to assess the effect of partner training on language impairment, psychosocial adjustment or quality of life • Partner training is probably effective for improving communication activities and or participation of people with chronic aphasia • Partner training appears to be effective for improving partner skills in supporting communication of people with aphasia.
Zhang, et al. 2017	CIAT	Yes	8	272	RCT	• CIAT may be useful for improving chronic post-stroke aphasia • Massed practice is likely to be a useful component • The role of constraint needs further exploration • Social interaction may be useful for enhancing the benefits

Table 7 AMSTAR rating

AMSTAR Items	Lavoie, Macoir & Bier, 2017	Simmons-Mackie, et al. 2016	Zhang, et al. 2017
1. Components of PICO provided?	+	+	+
2. Explicit report of review methods?	+	+	+
3. Study design selection justified?	+	+	+
4. 3. Was a comprehensive literature search performed?	+	+	+
5. Was there duplicate study selection?	+	+	+
6. Was there duplicate data extraction?	+	+	+
7. Listed and justification of excluded studies?	-	-	-
8. Were the characteristics of the included studies provided?	+	-	+
9. Risk of bias assessment completed?	-	+	-
10. Sources of funding reported?	-	-	-
11. Were the methods used to combine the findings of studies appropriate?	+	**N/A**	+
12. Impact of the Risk of bias considered in the evidence synthesis?	-	**N/A**	-
13. Risk of bias considered in the interpretation and discussion of evidence synthesis?	-	-	-
14. Satisfactory explanation of heterogeneity?	+	-	+
15. Was the likelihood of publication bias assessed and discussed?	+	-	+
16. Any conflict of interest reported?	-	-	-
Rating overall	**Low**	**CL**	**CL**

2.5 Strengths and Weaknesses

This overview included all Cochrane and non-Cochrane systematic reviews to ensure a thorough, overview of the aphasia intervention literature. Further, the inclusion of non-Cochrane reviews ensured the inclusion of all primary research designs. The literature from 2016 to April 2020 was searched to ensure no new interventions had been reported in RCTs. Therefore this overview was a systematic, comprehensive search for interventions for aphasia providing confidence that no intervention matching the criteria specified had been overlooked.

However, it is possible that additional interventions for aphasia published prior to 2016 may not have been identified as the search was limited to systematic reviews. Another weakness of the review was the inability to retrieve all reviews identified in the updated search due to limited library services at the time of completing the update. Whilst two independent reviewers selected the systematic reviews for inclusion in this overview to minimise bias, the weakness remains that only one reviewer completed data extraction and quality analysis which allowed only one interpretation of the data.

2.6 Summary

The overarching aim of this overview was to identify an intervention for aphasia that improves conversation through the remediation of spoken language, can be delivered intensively, is resource efficient, and has the best available evidence for use to underpin further research in the NHS.

Thirteen reviews were included in this review of systematic reviews. All interventions included in these 13 reviews were also included in the Cochrane review examining interventions for aphasia (28). The conclusions of the included reviews varied in the findings and were often more bold in claims of effectiveness than the Cochrane review of the same studies and interventions. The included reviews were almost all of critically low or low quality whereas the Cochrane review was considered a high quality review when rated with AMSTAR. Therefore, the low quality of the included systematic reviews may impact the confidence in the interpretation of the results given by these reviews. Whereas the high quality Cochrane review findings can be taken with good confidence.

Six interventions for aphasia that aim to improve conversation (CIAT/ILAT, M-MAT, PACE, Supported Conversation, Reciprocal scaffolding and Conversation partner training) were identified. It is interesting to consider that so few therapies were found that target conversation as the goals and perspectives of people with aphasia, discussed in Section 1.3.4, were found to be increased autonomy in maintaining friendships and social networks (30) and researchers reported that targeting conversation was a priority for people with aphasia (72).

Of these six interventions two interventions that aimed to improve conversation targeted the spoken language impairment caused by aphasia (CIAT/ILAT and M-MAT). The remaining four interventions targeted conversation through educating those around the person with aphasia (101), using alternative or augmentative forms of communication (99) to support the conversation of people with aphasia .

Three reviews had intensity of intervention delivery as the main focus of the review (14,75,85) whilst a further five reviews included intensity as part of the review outcomes. All these reviews including the Cochrane review stated that delivering interventions for aphasia intensively may be beneficial for people with aphasia (28,82–84,86). Furthermore, 17 of the intervention types included in this overview had been delivered with high intensity indicating that researchers have placed emphasis on assessing the effectiveness of interventions delivered in this way. Yet, the NHS has limited resource making it difficult to deliver interventions for aphasia intensively thus limiting the availability of these interventions to people with aphasia. It is surprising then that only four reviews examined efficient methods of delivering interventions for aphasia (14,28,82,89). All four reviews examined efficient

delivery in groups and only two reviews assessed delivery of interventions by non-professionals (14,28). Nine of the included interventions had been delivered in groups and eight had been delivered by non-professionals. Highlighting that less focus has been given to assessing efficient delivery of interventions for aphasia as compared to intense delivery of interventions in the research.

Both CIAT/ILAT and M-MAT met the first two objectives of this chapter. 1) Both interventions focus on using spoken language in conversation, and have been delivered in intensive schedules of more than five hours a week. 2) In terms of efficiency both CIAT/ILAT and M-MAT have been delivered in groups and CIAT/ILAT had additionally been delivered by non-professionals.

To meet objective three (finding the intervention with the best available evidence) GRADE assessments of both CIAT/ILAT and M-MAT were attempted. CIAT/ILAT was given a low rating within the GRADE system indicating that further research is required to determine the effectiveness of the intervention((28) See Appendix 5). M-MAT was not assessed through GRADE as no RCT data was available for the assessment. M-MAT was identified through the list of ongoing trials in the Cochrane review and an RCT level investigation of effectiveness is ongoing (132) Therefore, CIAT/ILAT was identified as the intervention that has the best available evidence for further research in the NHS. Whilst CIAT/ILAT has the best available evidence it is still weak and uncertainty remains in regards to its effectiveness. Brady et al. (2016) call for further well designed RCTs to clarify the impact of interventions delivered in groups, mediated by computers and delivered by volunteers. CIAT/ILAT is a clear candidate for a well-designed RCT building on its existing body of research and it hasn't yet been evaluated in the NHS. Therefore, further research is needed to determine the feasibility and acceptability of delivering CIAT/ILAT in the NHS and its effectiveness. The next chapter defines the key components of CIAT/ILAT and the development of assistant-volunteer led ILAT.

Chapter Three: A review of Intensive Language Action Therapy (ILAT) and development of a protocol for efficient delivery of ILAT

Chapter 2 found that CIAT/ILAT was a promising intervention for the treatment of post-stroke aphasia, but that its resource intensity means that further research is warranted to understand the feasibility and effectiveness of efficient methods of delivery such as assistant/volunteer-led group delivery. To exchange ideas about ILAT with scientists and practitioners, and in order to evaluate it, it is important to clarify its essential components. Part one of this chapter starts by reviewing key theoretical work, and identifies five categories of components: those targeting salience [language action embedding]; intensity and repetition [massed practice]; specificity [prompts and feedback]; use-it-and-improve-it [shaping and tailoring]; and, use-it-or-lose-it [constraint] which are said to trigger the hypothesised mechanism of action, Hebbian learning. A narrative review of evaluations of ILAT was completed using the TIDieR (Template for Intervention Description and Replication) framework, to organise and present how the components of ILAT identified in the theoretical review have been delivered. This informed how to deliver the components of ILAT for the development of the treatment manual. The second part of this chapter theorises the delivery of ILAT by assistants/volunteers, using TIDieR, a programme theory and logic model to describe the intervention to be evaluated.

Part 1: ILAT treatment theory and narrative review of ILAT studies

Intensive Language Action Therapy (ILAT) was first introduced in 2001 as Constraint Induced Aphasia Therapy (CIAT) or Constraint Induced Language Therapy (CILT). It was translated from Constraint Induced Movement Therapy to aphasia therapy by Pulvermuller et al (2001) (112). Since 2001, CIAT has been reported in the literature with differing interpretations of the intervention methods. Criticism arose surrounding the use of constraints (133), so in 2012 Difrancessco and Pulvermuller (57), released a methods paper describing and extending CIAT, renaming it Intensive Language Action Therapy and attempting to clarify methods and materials for faithful delivery of ILAT.

3.1 Aims and Objectives

The overarching aim of this chapter was to describe ILAT, its underlying theory, mode of action, its key components and describe the intended delivery of ILAT for the empirical research reported in chapters four to six of this thesis. The specific objectives were to:

a. clearly define the components of ILAT as described in the key theoretical literature and by the originator to inform a program theory;
b. identify how ILAT has been described in the literature and identify which primary research studies evaluate ILAT delivered in concordance with the current theory of ILAT including all essential components to inform the treatment protocol for ILAT used in this study; and,
c. develop a logic model for assistant/volunteer led ILAT within the NHS to articulate the way in which it is expected to work; and
d. describe a treatment protocol for the version of ILAT to be evaluated in this thesis.

3.2 Intensive Language Action Therapy: the theory

The United Kingdom Medical Research Council (MRC) recommend the use of theory to hypothesise underlying mechanisms and interactions during intervention development (134). Therefore, I read theoretical articles about ILAT (57,112,135,136), had extended conversations with its originator and observed ILAT being delivered in the originator's clinic in Berlin. The theoretical articles included the first report of ILAT (112), a subsequent methods paper detailing the ILAT methods (57) and, two articles that discussed the theoretical underpinning and neuroscience principles of aphasia treatment and ILAT (135,136). From this, a treatment theory (137) of ILAT was clarified and agreed by the interventions originator (see Figure 7).

ILAT is a set of techniques for the treatment of aphasia that emphasise massed practice, behaviourally relevant action-embedded language use and focusing and tailoring treatment to address the communication needs of the individual person with aphasia. ILAT is delivered in groups of two to four people with aphasia; two facilitators deliver the therapy. During ILAT people with aphasia sit behind screens to prevent showing cards or replacing verbal communication with gesture, and play language action games (LAG). Each game is a series of turns in which a participant requests or proposes an activity or object to another participant who then either accepts or rejects the request/proposal. On successful request the participants exchange cards and the next participant takes a turn. One facilitator plays the LAG with the people with aphasia. This facilitator is modelling game play and explicit rules to support people with aphasia learning the game. The second facilitator observes and ensures the game runs smoothly and supports any communication breakdown (138).

Pulvermuller et al (2001), when first reporting ILAT, reported that it was possible, with intensive massed treatment, three hours a day, using ILAT, to achieve improvements in chronic aphasia in a short period of time, only ten days. Participants (n=10) received 30 hours of ILAT over the course of

ten days. In terms of the pattern of recovery Pulvermuller et al (2001) reported improved naming and language comprehension on standardised assessment using the Aachen Aphasia Battery (139) that reached statistical significance ($p = 0.02$). Improvement in the use of everyday communication was measured by the Communication Activity Log (CAL) which was developed by Pulvermuller and confirmed through ratings completed by blinded clinicians (psychologist), that reached statistical significance ($p = 0.001$). Therefore, Pulvermuller et al (2001) concluded that improvements caused by ILAT were transferring to functional every day communication and reflected an improvement in communicative effectiveness (112). Difrancesco, Pulvermuller and Mohr (2012), describe communicative effectiveness as how successfully people with aphasia complete speech acts such as requesting, informing and making suggestions which are the speech acts of everyday interactions and conversations (57). These initial results were promising but further research was needed to determine the contributions of massed practice, constraint and behavioural relevance to understand the mechanisms of action for ILAT.

From a cognitive neuroscience perspective, constraint-induced therapies are underpinned by the principles of experience dependent plasticity (see Table 1) and force the use of the affected limb or communicative ability, through the use of a sling or barriers, materials and rules. This forced use is intended to combat learned non-use in which the affected limb or communicative ability continues to lose function as it is neglected in preference of the unaffected limb or more easily achieved communication method (25,140) Pulvermuller et al. (2008) clarify the process of non-use in aphasia stating that just as a stroke survivor will compensate for the affected limb by using the unaffected limb, as the easier way to achieve a task, so too the person with aphasia will use the communicative ability that is least affected to compensate for those communication abilities that are affected. For example, people with aphasia may gesticulate, use inexact or circumlocutory techniques, or use phrases that they find easier to say, to convey messages rather than articulating the specific words required for a communicative exchange leading to learned non-use. To combat learned non-use and improve communicative effectiveness Pulvermuller and colleagues, suggest that it is imperative that people with aphasia are induced to use words and language that would be routinely neglected (25,112,138). In the delivery of ILAT compensatory communication is shaped to increasingly complex and accurate language and focused through the following methods: barriers, to prevent the use of gesture, pointing or picture-based communication; materials that require exact language for effective communication; explicit rules, that require the use of phrases, politeness terms or complex language; and the therapeutic context, that provides modelling and repetition to increase communicative effectiveness. Materials, explicit rules and modelling can be tailored to the individual person with aphasia allowing each person to operate at the upper most edge of their communicative competence. To avoid continual failure and increased frustration, which would result in the further

reinforcement of learned non-use, each person with aphasia is required to gradually and incrementally improve language efficiency. Pulvermuller et al (2001) have termed this approach 'shaping' and the gradual, incremental steps as 'successive approximations' (112,138). Thus, the aim of ILAT is not to constrain non-verbal communication but instead to encourage verbal communication. Difrancesco, Pulvermuller and Mohr (2012), assert that the production of non-verbal communication in conjunction with, or to support verbal communication is desirable but that the replacement of verbal communication with non-verbal communication should be avoided in therapeutic attempts to improve verbal communication effectiveness. Further, the authors are careful to state that non-linguistic actions are not prevented or constrained, as these forms of communication occur in normal communication and in fact may support word finding difficulties, but instead isolated use of non-verbal action in replacement of verbal communication should be avoided. Where this occurs barriers, shaping, modelling and positive reinforcement should be used to encourage verbal communication (138).

From a neuroanatomical perspective, neural networks are strengthened when neural networks are activated frequently and simultaneously as goes Hebb's axiom 'neurons that fire together - wire together' (141). These neural networks that connect the circuits for controlling articulators and those that perceive these signals therefore develop the neural network required for words and their articulatory patterns to be accurately produced. Even more intricately the neural networks for the perception and production of words are often used in context of the referent objects or actions thus further building the broader neural network to include the visual and motor cortex. Therefore, the implications for neurorehabilitation are that it is imperative that these neural networks are co-activating, thus strengthening the neural network for the accurate and complete production of words, phrases and sentences (138). This process of Hebbian learning may also be active in the use of syntax for more complex speech acts (25). Conversely the anti-Hebbian learning should be actively avoided, in that the firing of parts of the neural network in isolation of other parts of the larger network will result in a weakening of the neural networks (141). For example, people with aphasia may activate the word concept but be unable to activate the neural network containing the linguistic information required to name the word. Continually attempting to activate the concept without activating the neural network could lead to a further anti-Hebb learning that will weaken the concept-word connection (136).

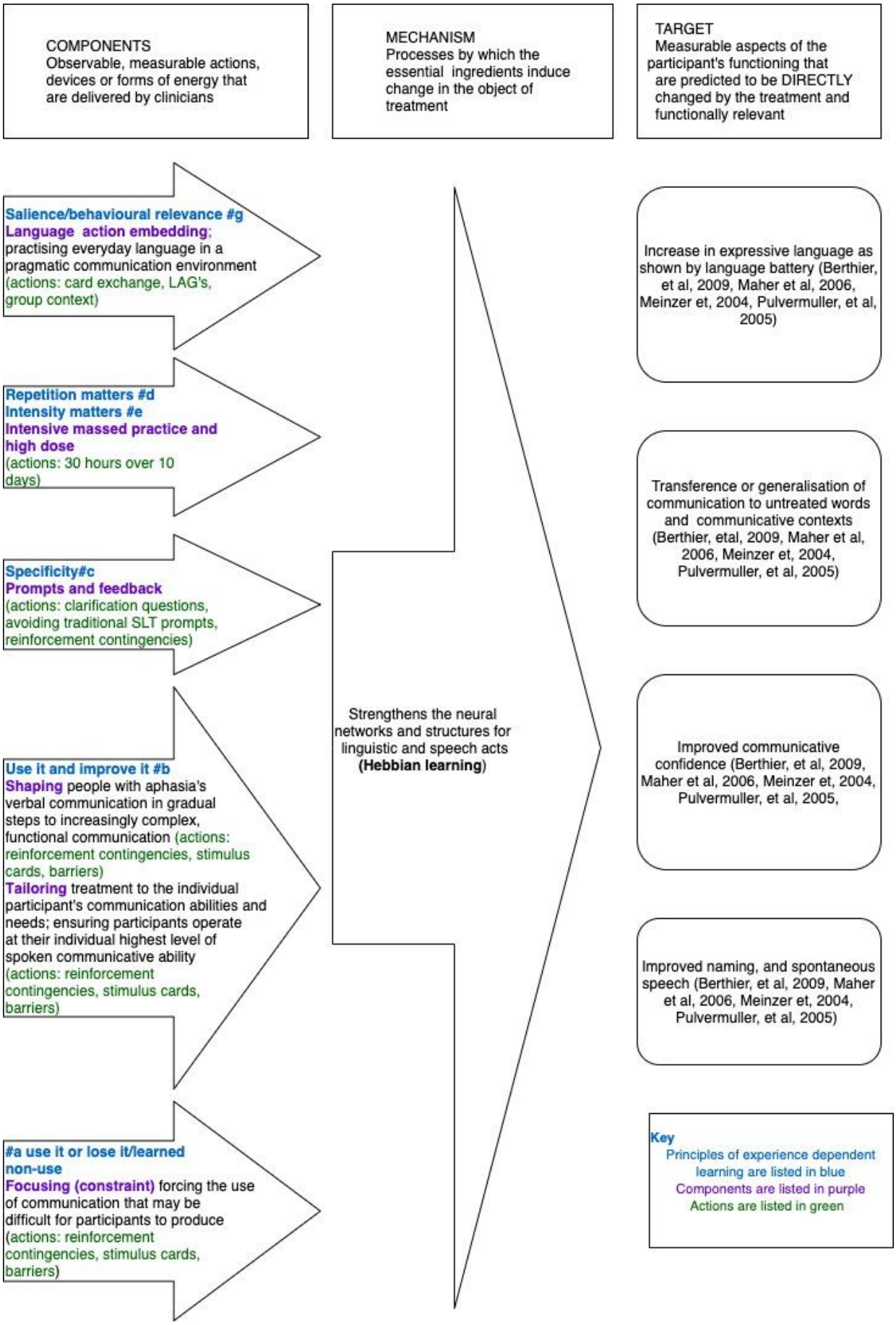
In the case of aphasia and language production; combining the referent object or action and the linguistic form or word causes the co-activation of the diverse neural networks including linguistic visual and sensorimotor neural networks (142). The more often these neural networks are co-activated the stronger these connections become. The importance of the principle of co-activation

for the treatment of aphasia lies in the repeated and consistent broad activation of diverse neural networks allowing the strengthening, repair and rewiring of damaged areas of the neural network. Conversely, activation of independent parts of the neural networks results in anti-Hebb learning further weakening the already damaged connections between words, referent objects and actions (57). Figure 7 depicts the ILAT treatment diagram that shows the underlying mechanisms of action of ILAT as described in the theoretical literature and confirmed by the originator. The first column of arrows describes the essential observable actions for the delivery of ILAT. These are the key ingredients that ensure ILAT is delivered faithfully to the original design and should therefore trigger the proposed underlying mechanism of action. The observable actions have been mapped on to the principles of experience dependent learning (see Table 1 on pg. 22). Each category of components relates to a principle of experience dependent learning and contains the components and the actions, activities, and resources that were used to deliver each component of ILAT. The five categories were:

(1) salience (component: language action embedding; actions: card exchange, LAG's and the group context);
(2) intensity and repetition (component: massed practice, action: ILAT delivered for 30 hours over ten days);
(3) specificity (components: prompts and feedback, actions: using clarification questions and reinforcement contingencies);
(4) use-it-and-improve-it (components: shaping and tailoring actions: reinforcement contingencies and stimulus materials); and,
(5) use-it-or-lose-it (component: constraint/focusing, actions: barriers, reinforcement contingencies and stimulus cards)

The next section contains a description of the program theory that is a discussion of each category of components and the actions that target each of the five principles of experience dependent learning outlined above.

Figure 7 ILAT Treatment Diagram



3.2.1 Components targeting salience

In order for the brain to allocate resource to the repair of the damaged neural networks the intervention must be sufficiently salient to cause the brain to allocate increased attention to the desired outcome and therefore strengthen the neural networks. This is because the brain pays attention to what it deems to be important or rewarding (55). Consequently, any intervention needs to be rewarding and important to the person with aphasia for the brain to give the attention required for learning. ILAT attempts to address salience through increasing behavioural relevance through the use of language action embedding. The actions that achieve this component are the LAGs, stimulus cards and the group setting (57).

3.2.1.1 Language action embedding

ILAT attempts to encourage the use of specific and accurate spoken output within the context of everyday communicative exchanges. For example, requesting, storytelling and giving directions (122). DiFrancesco, Pulvermuller and Mohr (2012), describe this concept as 'action-embedded'. Meaning that language use is relevant for daily life and practised in action contexts, thus putting the production of words back into everyday communicative context and increasing the behavioural relevance of ILAT (138). Pulvermuller and colleagues reported using Wittgenstein's (1953) concept of 'language games' to form the basis of the communicative interactions in ILAT (112,143). These games consist of requesting, storytelling, giving directions and joint planning which mimic normal everyday communicative exchange and form the language action games for ILAT (25).

Difrancesco, Pulvermuller and Mohr (2012) further describe the language action component of ILAT stating that language use must be placed in action contexts as language and action are represented in tightly interwoven neural networks. To clarify, in everyday language, words and their referent objects or actions are frequently used together, simultaneously activating the neuronal circuits for the visual or motor systems as well and the language and associated systems (112). It is theorised that ILAT uses Hebbian learning, the concept that 'neurons that fire together wire together' as the underlying mechanism of action (57). Therefore, the aim of ILAT is to strengthen and repair neural networks through the activation of the entire language system including referent objects, actions and words and the motor, visual and other sensory networks (136,141). Studies involving brain imaging reported that ILAT was able to reorganise neural netowrks to improve communication function (144). ILAT attempts to facilitate simultaneous firing of the combined neural networks using Language Action Games that require participants to formulate requests or plans with other participants and then explicitly deny or accept the request or plan and physically exchange the cards(57,112,135). The co-participant then either refuses or accepts the request or proposal and physically hands over the card to the other participant. Therefore, the action of handing over the

card and also the active acceptance or refusal of a request or proposed activity is a pragmatic form of action embedding that aims to co-fire action related neural networks in conjunction with the damaged semantic neural network. For example, one participant may have a picture depicting playing tennis. This participant would then propose playing tennis with a co-participant. If that co-participant has a card depicting tennis they would accept the proposal and exchange the card (57).The more obvious language components of making a request such as formulating the sentence and using the correct words are attempting to directly activate the language system whilst perhaps less obvious, the request or plan itself is attempting to more broadly activate the motor and sensory neural networks due to the action and experience content of the request. In contrast, to simply name an item out of its context and not in response to an action may only activate the language neural networks(112).

3.2.2 Components targeting repetition and intensity

Pulvermuller and colleagues posit that intensity and repetition are achieved through massed practice which encourages increased and repetitious opportunities for Hebbian learning or the strengthening of those neural networks that are coactivated (112,138). ILAT is designed to avoid independent activation of single neural networks through the use of procedures and materials embedded in a behaviourally relevant, language action context and massed practice for several hours per day allows for repeated co-activation. Pulvermuller et al (2001), in the first published study of ILAT compared intensive treatment using ILAT delivered three hours a day for ten days to usual care delivered on a non-intensive treatment schedule over four weeks and found that ILAT produced statistically significant improvements in aphasia severity and functional communication that were not found in the usual care arm (112).

3.2.3 Components targeting specificity

People with aphasia have difficulties finding the words or accurately conveying information. ILAT, by its design, requires the accurate production of specific language for success (112). Consequently, there are lots of opportunities for people with aphasia to improve communicative effectiveness. However, there are also lots of opportunities for communication breakdown and failure. This is where the role of the clinician is essential to facilitate successful communication exchanges through the use of the components prompts and feedback.

3.2.3.1 Prompts and feedback

Pulvermuller, et al. (2001) reported providing reinforcement when participants met the constraints or rules set for their individual lee of competence. However, no further description of feedback or prompting to repair communication breakdown was reported (112).

Difrancesco, Pulvermuller, and Mohr, (2012) clarify the process of prompts and feedback in ILAT through using clarification questions within the language action game and feedback that is naturally received through the success or failure of matching the cards. They also state that the co-therapist not actively participating in the ILAT games should help participants who have a difficulty with a specific card or communicative move but do not give details of what support should be provided. Further clarification of prompts and feedback was sought by the research SLT with the originator and through observations of LAG's delivered in the originator's clinic. Professor Pulvermuller encourages the therapist playing the game to clarify any breakdown through questioning as a form of prompts and feedback. For example, asking open questions such as where, when, what, how questions to gather information about the card being discussed. If these questions are not easily answered by the participant then the clinician can ask forced choice questions for example 'would you find it inside or outside, is it large or small?' Pulvermuller emphasised that traditional prompts often used in SLT such as phonemic, giving the first sound, or semantic, giving a clue about the card, should be avoided as these types of prompts are not behaviourally relevant; as in an everyday communication exchange the communication partner does not know the word trying to be produced so cannot provide these prompts but they may ask clarifying questions to resolve communication breakdown. Further, practising answering these questions in the therapeutic context may encourage people with aphasia to use this kind of descriptive information in everyday communication exchanges (57). On observation of the originators clinic it was evident that using the clarification questioning technique resolved communication breakdown in the majority of LAG exchanges.

3.2.4 Components targeting 'use-it-and-improve-it'

Behavioural relevance and the axiom 'we get better at what is practised' or use-it-and-improve-it is a well discussed principle in the treatment of aphasia and pragmatic SLT (55). If the ultimate goal of SLT interventions for aphasia is to improve the communication of people with aphasia in every day conversations then therapies need to be behaviourally relevant to that goal. Therefore, ILAT has attempted to mimic the everyday exchanges of requesting, planning, story-telling and giving directions in a therapeutic context. 'Use it and improve it' emphasises the idea that you improve at what you practice (55). This principle encompasses two ideas. The first, in the case of aphasia practising skills like naming a picture or completing a phrase will improve the ability to achieve those skills but will not necessarily improve your ability to use words in sentences or have a functional conversation. Therefore, if the goal of an intervention is to improve having conversations then the intervention must in some way simulate having a conversation. The second idea is that the specific vocabulary used as the stimulus in the intervention will improve the ability to say those words and not necessarily mean that words that were not treated in the intervention will be easier to say.

Therefore, to have the greatest impact, words that are treated in the intervention must be the words that are relevant to the individual with aphasia (145). ILAT attempts to target this principle through the components shaping and tailoring.

3.2.4.1 Shaping

Pulvermuller et al. 2001, describe shaping as the gradual transition from communicative behaviour that is more easily produced or characteristic of the person with aphasia to more linguistically competent communicative behaviours through the use of small steps that gradually require increased communicative competence. Shaping is achieved through the use of materials that require increasingly more complex linguistic output and through the tailoring of individual rules that participants adhere to. For example materials may require the participant to produce words about, number, colour or size of an object i.e. a red apple vs. two green apples or to produce the desired words within a carrier phrase or syntactic structure such as 'may I have the…' or use politeness terms. The length of the communication output can also be shaped from using any utterance (e.g., clock?), producing a two word phrase (e.g., pass clock), a grammatically correct sentence (e.g., could you pass me the clock?) and finally to a complex grammatical sentence (Could you pass me the clock that is orange?). In this way ILAT induces participants 'to use it and improve it' operating at the upper limit of their communicative competence and to continue to expand this throughout the course of treatment (112). Difrancesco, Pulvermuller and Mohr (2012) explain that through modelling the desired communicative outcomes participants will attempt to use these more complex syntactic structures during progression through the ILAT course. These rules can also be explicitly explained to participants and reinforced through feedback contingencies (57). Improving communicative competence through increasingly complex and accurate phrases and sentences is theorised to allow this more complex and accurate language to be used in functional everyday conversation as the speech acts used in ILAT, requesting and planning, simulate those that occur in conversation. For example requesting an item or information, or planning to do an activity or event and information giving with specific vocabulary or complex details are all LAG tasks and conversation structures (146). Thus, ILAT attempts to make therapy tasks as similar to everyday conversation as possible so participants are practising the skill that is necessary for everyday life (135). As discussed in section 3.4 shaping is also targeting the principle use-it-or-lose-it as it incrementally moves participants from easily achieved spoken language to more accurate and complex language thus preventing the avoidance of more difficult structures and combating learned non-use/use-it-or-lose-it (57).

3.2.4.2 Tailoring

The use of individualised rules for completion of Language action games such as using a carrier phrase, politeness terms or another participant's name are used to tailor the intervention to the

individual participant's needs (112). Further rules such as using descriptive words or certain linguistic structures have also been reported in the literature (147). There is also the ability for ILAT materials to be tailored to the individual participants interests further improving the 'use-it-and-improve-it' component as well as the salience for the individuals with aphasia (145). Tailoring also ensures that each participant is using the full range of verbal communication available and that the individual is operating at the upper limits of their individual communicative abilities(57).

3.2.5 Components targeting use-it-or-lose-it

In attempts to combat learned non-use Pulvermuller, et al. 2001 report that it is essential that people with aphasia attempt to use linguistic structures and words which they find difficult and would usually avoid to encourage the growth and repair of neglected neural networks. It is therefore important that participants make every attempt to produce linguistic functions rather than avoiding them (112). ILAT attempts to remediate learned non-use through the use of constraints/focusing and barriers.

3.2.5.1 Constraint/focusing and barriers

In the early definition of ILAT known as Constraint Induced Language Therapy (CILT) or Constraint Induced Aphasia Therapy (CIAT) constraint was defined as preventing all non-verbal communication through the use of barriers, materials and rules that prohibited non-verbal communicative attempts to force the use of verbal communication (112). In 2012 Difrancesco, Pulvermuller and Mohr, further clarified the role of constraint in the delivery of CILT/CIAT and renamed the intervention Intensive Language Action Therapy, stating that gesturing or pointing behind the barriers did not need to be prevented as these gestures could support word finding difficulties. Difrancesco, Pulvermuller and Mohr, softened and relabel the term 'constraint' to 'focusing' (57).In fact, the component of language action embedding and Hebbian learning would support the use of gesture in enhancing the firing of movement related neural networks during attempts to also activate the linguistic neural network (57,136,141).

Hebbian learning is the proposed underlying mechanism of action for ILAT and is represented in the second column of the treatment diagram (Figure 7). It is hypothesised that combining these five components will co-activate broad neural networks in conjunction with the specific neural networks containing semantic and linguistic information to achieve Hebbian learning for the repair and rewiring of damaged neural networks (For a detailed description of Hebbian learning please see section 3.2 Intensive Language Action Therapy: the theory). The final column of arrows in the treatment diagram (Figure 7) shows the outcomes reported in the literature

3.4.2 Study ***characteristics***). These outcomes will be discussed in detail following the narrative review of studies of constraint-induced therapies in the literature.

3.3 Narrative review of studies evaluating ILAT

A narrative review was conducted to identify how ILAT has been described in the literature and identify which primary research studies evaluate ILAT delivered in concordance with the current theory of ILAT including all essential components to inform the treatment protocol for ILAT used in chapters 4-6 of this thesis including whether and how they delivered the essential components of ILAT.

3.3.1 Methods

The methods for this review were conducted in accordance with the Cochrane handbook of systematic reviews (78). However, as the objective of this review was to compare and analyse the design, delivery and outcomes of ILAT a narrative synthesis was employed (148) rather than a statistical analysis of effectiveness of ILAT.

3.3.2 Search Strategy

A systematic search strategy was employed to ensure the narrative review of ILAT was comprehensive. The search terms were developed through a 'pearl growing' exercise (the key words of articles identified by the initial search terms were checked to identify any additional terms to include in the search strategy) and an information specialist from the health services library was consulted in the development of the search terms (see Table 8 for terms and Appendix 6 for full search strategy). Three databases were selected for the review as a diverse range of disciplines are involved in the delivery of rehabilitation for aphasia. These databases were Medline via Ovid 1946 to present, PsychINFO (APA PsycNET) and CINAHL (EBSCO). Hand searching of reference lists was also completed to ensure all studies detailing ILAT were included. The searches were conducted in January 2019.

Table 8 Search terms

Population	Intervention
Aphasia.mp. or exp Aphasia, Broca/ or exp Aphasia, Wernicke/ or exp Aphasia/ or exp Aphasia, Conduction/Dysphasia.mp Exp Stroke, Lacunar/ or Exp Stroke/ or stroke.mp. Exp Chronic Disease/px, rh, th [Psychology, Rehabilitation, Therapy] Stroke AND Aphasia	Speech therapy.mp. or exp Speech Therapy/ Speech-language pathology.mp. or exp Speech-Language Pathology/ exp Group Processes/ Intensive.mp. Constraint-induced. Mp Intensive AND Group

3.3.3 Study Selection

All titles and abstracts generated by the search strategy were screened using the eligibility criteria by a single reviewer. All records identified by database searches were uploaded into a database (Covidence Systematic Review Software, Veritas Health Innovation, Melbourne, Australia. Available from: www.covidence.org) to identify and remove duplicates. The records were initially screened using the title and abstract. The following criteria were used for inclusion and exclusion in this review:

Inclusion criteria:

2. Research examining the effectiveness of CILT/CIAT/ILAT
3. Research related to aphasia caused by stroke
4. Research including primary data
5. The report was published in English
6. Research included adults (18 years+)
7. All study designs were included.

Exclusion criteria

8. Research reports that used primary data from previously reported research.
9. Review research reports were excluded if they did not contain any primary data

If eligibility was unclear from the title and abstract, the full text report was accessed and screened using the eligibility criteria.

3.3.4 Quality of included studies

The quality of the intervention description was assessed using the TIDieR checklist for intervention reporting (149). However, as the purpose of the review was to determine how ILAT had been reported in the research studies and not to determine intervention effectiveness, the degree of bias was not assessed.

3.3.5 Data extraction

The TIDieR checklist (149) was used to extract the data regarding intervention reporting (see Appendix 7). The 12-item TIDieR checklist aims to assess the completeness of intervention reporting to allow the reliable implementation of interventions into clinical practice (see Table 9 (149)). Items included population of aphasia participants including age, time post onset and severity of aphasia; name of the intervention; comparator where relevant; design of the research; delivery dose; outcome measures and any considered statistically significant following treatment; follow up time frame if any; all elements of the intervention methods particularly the key elements; constraint, barrier use, prompting/feedback, shaping and individualisation; and any description of the underlying mechanism/theory for ILAT.

3.3.6 Narrative Synthesis

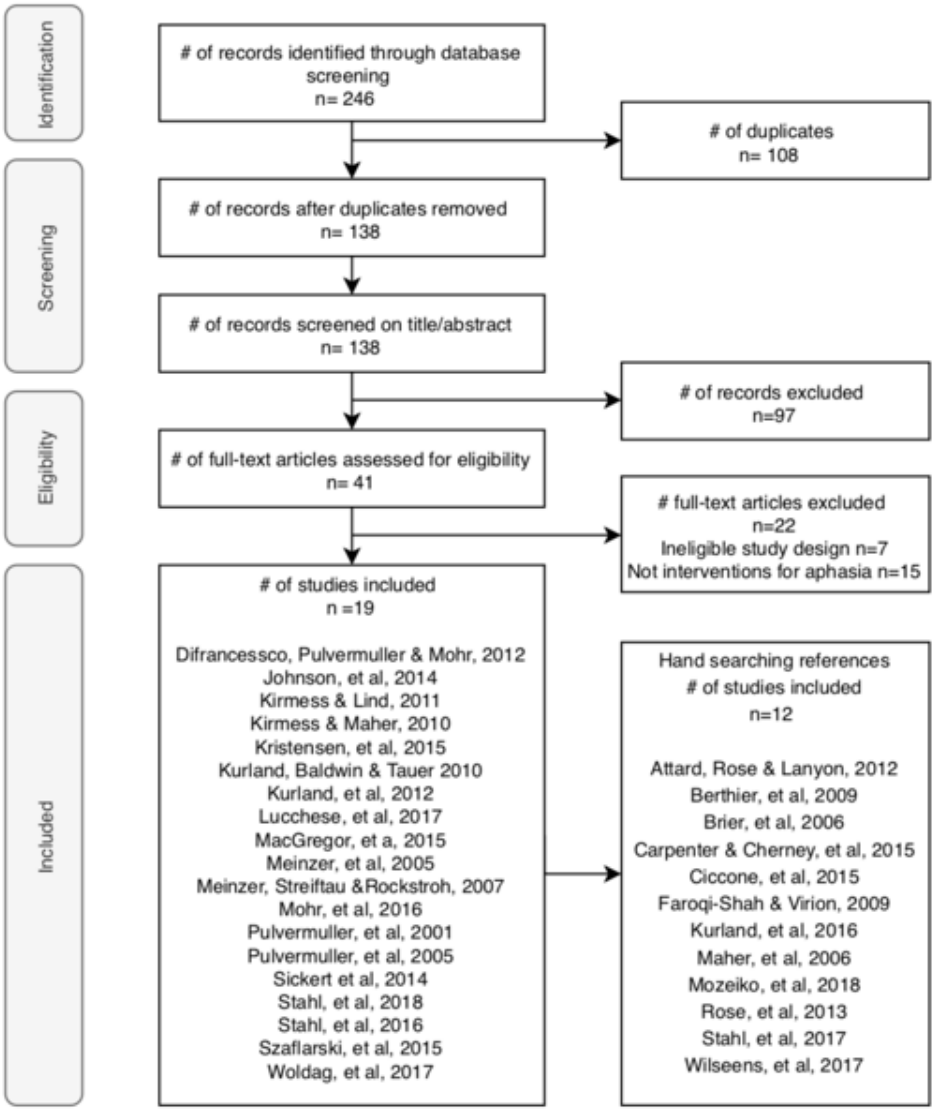
The ILAT treatment diagram identified the essential components of ILAT (see Figure 7) and all included studies were assessed against these five component categories (plasticity principles); targeting salience (language action embedding and behavioural relevance), targeting intensity and repetition (massed practice), targeting specificity (prompts and feedback), targeting use-it-and-improve-it (shaping and tailoring), and, targeting use-it-or-lose-it (constraint, barriers and learned non-use) to determine the level of concordance with the theory of ILAT. This data was tabulated, counted and discussed (see Table 11 and section 3.5).

3.4 Results

3.4.1 Included Studies

246 studies were identified through the search strategy described in section 3.3.2 Search Strategy. Once duplicates were removed 138 studies remained. 97 were excluded at title abstract screening due to ineligible study design, population or intervention. A further 22 were excluded at full text screening due to not meeting inclusion criteria for study design (n=6) or intervention (n=15). This left 19 studies for inclusion in this review. Hand searching of reference lists within the included studies elicited a further 12 studies that were eligible for inclusion in this review, resulting in inclusion of a total of 31 studies (see Figure 8).

Figure 8 Study flow (PRISMA) diagram



3.4.2 Study characteristics

Table 9 summarised the characteristics of the included studies. Of the 31 studies included 12 were RCTs (two with a cross-over design), nine were pre/post-test design, seven were case studies, one reported a non-randomised design and one reported a single case experimental design. The number of participants varied from a single case (114) to 100 participants in a RCT ((150) Woldag, et al. 2017). Participant age ranged from 26 years to 84 years and time post aphasia onset from five days to 20 years. Aphasia severity was rated as ranging from mild to severe.

The intervention was identified by the following names CILT, CIAT, ILAT and seven variations were described as CILT plus, CIAT plus, CILT delivered by laypersons, moderate intensity ILAT, CIAT + Memantine, CILT +grammatical and CIAT II. As ILAT is the current name for this group of constraint interventions, for simplicity, the intervention will be referred to as ILAT- based for the remainder of this review. Dependent on study design comparators were identified as conventional therapy,

naming therapy, BOX therapy, conventional group therapy, PACE, usual care, M-MAT and individual impairment-based therapy.

Table 9 showed that dose varied from 45 minutes to four hours a day, delivered from three days a week to six days a week and was distributed over as little as six days to as long as five weeks. 14 of the 31 studies reported the original dose, specified by Pulvermuller (the originator), of three hours a day for ten days totalling 30 hours of treatment. One study (151) repeated the dose of three hours a day for ten days for a total of 60 hours of ILAT-based intervention. Kurland et al (2012), (152) reported a two week treatment period but did not specify the number of hours ILAT-based intervention was delivered. Two studies reported delivering ILAT-based intervention less intensively for between one and two hours a day (153) (154). Ciccone and colleagues (147) reported a less intensive schedule of 45-60 minutes a day over a longer treatment period of four to five weeks.

Outcome measures used varied dependent on the country of origin and language spoken. Measures of the aphasia outcome included impairment based measures such as naming tests, picture descriptions, sematic fluency tests, story re-tell, conversational samples and entire aphasia batteries, commonly the Western Aphasia Battery (155) and the Boston Diagnostic Aphasia Examination (156), and measures designed to assess functional communication such as the Communication Activity Log (112) or the Communicative Effectiveness Index (157). The full list of outcome measures used in the evaluation of ILAT-based interventions can be seen in Table 9. Interestingly, given the goal of ILAT is to improve conversation, it is surprising that half of the included studies did not measure communicative effectiveness or conversation. Of those studies that did measure communicative effectiveness a wide range of measures were used including, functional measures such as the Communicative Effectiveness Index and Communication Activity Log as well as conversational samples or discourse analysis. Two studies reported using a narrative discourse or story retelling (71,158).

Table 9 Study Characteristics

Study	Study design	n	Population	Intervention	Dose	Outcomes Measures	Results	Maintenance
Attard, Rose & Lanyon, 2012	Case study	2	Age: 55 & 58 TPO: 82 & 117 months Mild and Mod	CIATplus M-MAT	26h over 2 weeks (3.25h 4 days a week)	WAB AQ CETI Scenario Test BNT	M-MAT and CIATplus equally efficacious No clinically or statistically significant changes were found	3 months
Berthier, et al. 2009	RCT double blind, placebo controlled	28	Mean Age 53.7 (36-65) TPO 6.4 Mild, mod, severe	CIAT + placebo Placebo only Memantine only CIAT + Memantine	30h over 2 weeks (3h a day)	WAB CAL	Memantine and CIAT improved aphasia severity and best outcomes were seen with CIAT+ memantine in aphasia severity (WAB AQ) and communicative activities (CAL)	16 weeks 18 weeks 20 weeks 24 weeks
Breier, et al. 2006	Pre/post test	5	Age 62 (52-73)years TPO: 46 (21-70) months Mod, severe	CILT	36h over 3 weeks (3 hours a day 4 days a week)	CIU WAB	3 participants had a clinically meaningful improvement in CIU	-
Carpeneter & Cherney, 2015	Pre/post test	9	Mean Age 58 (37- 76) TPO: 29 months (11 – 68)	CIAT Usual Care	1 hour a day for 10 days 1 hour 1to1 for 10 days	BDAE Naming task (trained and untrained)	Small-medium ES on untrained items (naming task) in the CIAT over usual care	-
Ciccone, et al. 2016	RCT	20	Mean age: 72.6 years (range not reported) TPO: 5.6 days (range not reported) Mild, mod, severe	CIAT Individual impairment based therapy	45-60min per day for 4-5 weeks (15-20 h completed over 20 sessions)	WAB AQ Discourse analysis (CIU) SAQoL	Statistically significant improvement in aphasia severity (WAB AQ) and improved quality of life (SAQoL) There was no statistically significant difference between CIAT and individual therapy	3 months
Difrancessco, Pulvermuller & Mohr 2012	Case study	2	Age: 40 & 73 TPO: 26 & 57 Mild	ILAT	30h over 2 weeks (3h a day)	BDAE BNT CAL Discourse analysis Error rates	Statistically significant Improvement in naming (BNT) Increase in the amount and quality of communication	-

						Reaction time	(CAL) Time taken to produce critical words in LAGs improved (reaction time)	
Faroqi-Shah & Virion, 2009	Case study	4	Age:44-66years TPO: 5-23 months Mild, Moderate	CILT CILT + grammatical	24h over 10 days	WAB AQ BNT Verb subtest of OANB VIT Cinderella story narration Conversation sample	Small improvement in aphasia severity (WAB AQ), object, and action naming (OANB, BNT, VIT)	3 months
Johnson, et al. 2014	Pre/post test	4	Mean age 71 (60-83) TPO 45 months (15-96)	CIAT II	45h over 3 weeks (3h a day)	VAL WAB-R	Significant improvements in amount of speech (VAL)	-
Kirmess & Lind, 2011	Case study	3		CILT	30h over 10 days (3h a day)	VOST NGA Object naming test – PALPA TROG-2	Medium-large ES on all outcomes	3 months 6 months
Kirmess & Maher, 2010	Pre/post test	3	Age: 89, 43 & 68 TPO 40, 42 and 58 days Mild, mod, severe	CILT	30h over 10 days (3h a day)	NGA TROG-2 VOST PALPA 54 Cookie Theft Self-report questionnaire	Improvement in expressive speech (words per minute NGA, VOST, PALPA 54) Self-report questionnaire mostly positive with differing opinion re: intensity	3 months 6 months
Kristensen, et al. 2015	Prospective multiple case study (A-B design)	11	Age: 59 (43-67) years TPO: 58 (46-109) days Not reported	CIAT (B) Usual Care (A)	30h over 10 days (3h a day)	WAB CETI CEP	An 'add on' effect was seen in the CIAT group, improvement in aphasia severity reached clinical significance but not statistical significance (WAB AQ) across all treatment periods Statistical significant improvement on the CETI	3 months
Kurland et al. 2016	RCT	24	Age:66.8 (43.7-81) years TPO: 28 (7-142) months Mild, mod, severe	CIAT PACE	30h over 10 days (3h a day)	BDAE BNT PICA Picture Naming	CIAT group showed improvement in naming trained and untrained (picture naming. BNT) over PACE group however it was	-

							not statistically significant	
Kurland, et al. 2012	Case study	2	Age 79 & 71 TPO: 6 months & 9 years	CIAT PACE	2 week treatment period	Naming Task BDAE	CIAT pariticipants produced more words accurately than the PACE group	7 months
Kurland, Baldwin & Tauer, 2010	Case study	1	Age: 55 years TPO: 3 years Moderately severe	CILT PACE	30h over 10 days (3h a day)	BDAE Naming Task OANB	More items 22/48 were named correctly after CILT whereas 9/48 were named correctly after PACE Untrained items showed no improvement	6 months
Lucchese, et al. 2017	Pre/post test	10	Mean Age: 51.2 (32-73) years TPO: 88.6 (30-245) months Mild, mod, severe	ILAT	42h (3.5h a day 4 days a week for 4 weeks)	AAT	Statically significant improvement of spontaneous speech, repetition, language comprehension and naming (AAT)	-
Macgregor, et al. 2015	Pre/post test	12	Mean age: 57 (26-76) years TPO: 81.6 (234-17)months Mild, mod	ILAT	30h (3h a day over 10 days)	BDAE	Statistically significant improvement in the naming (BNT, TT) and auditory comprehension (BDAE)	-
Maher, et al. 2006	Pre/post test Prospective, repeated measures pilot study	9	Mean Age: 58 (40-73) TPO: 35 (14-72) Mild, mod, severe	CILT PACE	24h (3h a day 4 days a week for 2 weeks)	WAB AQ BNT ANT Narrative discourse sample	Statistically significant improvement in aphasia severity (WAB, AQ), naming (BNT) and ANT Improved expressive language (WAB) Improved story retelling (narrative discourse)	1 month
Meinzer, et al. 2005	Non-randomised	27	Mean Age 52.1 (18-80) TPO: 47.9 months (12-116) Mild, mod, severe	CILT CILTplus	30h over 2 weeks (3h day)	AAT CETI CAL	Statically significant improvement of spontaneous speech and naming (AAT) Improved communicative effectiveness (CETI and CAL) Improved communicative confidence (CAL) across both groups	6 months

Meinzer, Streiftau & Rockstroh, 2007	RCT	20	Mean age 56.1 (35-72) years TPO: 38.6 (6-79) months Mild, mod, severe	CIAT Therapist CIAT layperson	30h over 10 consecutive days	AAT	Statistically significant improvement in aphasia severity (AAT) no between group differences found	-
Mohr, et al. 2016	Pre/post test	14	Mean Age: 56.93 (26-76) years TPO: 6.13 (1.6-19.5) years Residual, mild, mod, severe	ILAT	3-4 h a day over 2 consecutive weeks	BDAE TT BNT CAL	Statistically significant improvement in naming (BNT) and sentence comprehension (TT) Significant improvement in communication function (CAL)	-
Mozeiko, et al. 2018	Single-subject experimental design	6	Age: 47-79 years TPO: 31-58 months Mild, mod, severe	CILT	60h (3 hours a day for 2 weeks 5 week break then repeated 3hours a day for 2 weeks)	WAB-R AQ BNT TT (revised)	Clinically significant improvement in aphasia severity (WAB AQ) and naming (BNT)	8 weeks
Pulvermuller, et al. 2001	RCT	17	Mean age 55.4 (39-72) years TPO: 98.2 (2-172) months Mild, mod, severe	CIAT Conventional Therapy	30h over 10 working days (3-4h a day)	AAT CAL	Statistically significant improvement of spontaneous speech, repetition, language comprehension and naming (AAT) naming (AAT) and communication function (CAL) in the CIAT group not found in the conventional therapy group	-
Pulvermuller, et al. 2005	Pre/Post test	10	Mean age: 54.4 (39-72) years TPO: 90 (16-233) months Mild, mod, severe	CIAT	30h over 10 working days (3h a day)	AAT TT	Statistically significant improvement of spontaneous speech, repetition, language comprehension and naming (AAT)	-
Rose, et al. 2013	Single subject, multiple baseline, cross-over treatment	11	Mean Age: 58 (39-74) years TPO: 44 (17-88) months Mild, Mod, Severe	CIATplus M-MAT	32h over 2 weeks	WAB AQ Noun and verb naming	Clinically significant improvement in aphasia severity (WAB AQ) Mean medium ES for noun and verb naming no between group differences found	1 month 3 months

Sickert, et al. 2014	RCT Randomised, single blinded, parallel group	100	Mean age: 60.4 (41-81) years TPO: 36.7 (28-84)days Mean age: 60.2 (34-84) years TPO: 32.9 (28-112) days	CIAT Conventional therapy	2 h day over 15 days	AAT CAL	Statistically significant improvement of spontaneous speech, repetition, language comprehension and naming (AAT) communication function (CAL) no between group differences found	2 months 12 months
Stahl, et al. 2016	RCT Cross-over	18	Mean Age: 54.4 (32-73) Years TPO: 105.8 (13-239) months Severity: Mild, mod, severe	ILAT Naming Therapy	3.5h a day over 6 working days	AAT TT	Statistically significant improvement in language function (AAT) in the ILAT group that was not seen in the naming therapy group	-
Stalh, et al. 2017	RCT Cross-over	14	Mean Age: 50 (32-73) years TPO: 109 (31-239) months Severity: mild, moderate, severe	ILAT Naming Therapy	3.5h over 6 working days	AAT CAL	Statistically significant improvement in communication function (CAL) for the ILAT group that was not found in the naming therapy group	-
Stahl, et al. 2018	RCT Randomised parallel group blinded assessors	30	Mean age: 60.1 (SD 15.3) years TPO: 65.2 (SD: 64.3) months	ILAT mod intensity ILAT high intensity	2 h day 3 x a week for 6 days separated by a weekend (2 doses = 12 days) 4h a day 3 x a week for 6 days separated by a weekend (2 doses = 12 days)	AAT ACT	Statistically significant improvement in language function (AAT), and requesting/naming (ACT) high intensity therapy did not result in additional improvement	-
Szaflarski, et al. 2015	RCT	24	Mean age: 57 (SD: 13) years Mean TPO: 38 (SD: 59) months Aphasia: Mild, mod, severe	CIAT No-intervention	4h a day 10 working days	TT BNT COAWT SFT PPVT Mini CAL	Statistically significant improvement in language function (AAT), and requesting/naming (ACT) in the ILAT group over the no-intervention group	12 weeks
Wilssens, et al. 2015	RCT	9	Age: 66.8 (54-81) years TPO: 56.9 (17-138) months	CIAT BOX	3 h a day 10 working days	AAT BNT PALPA	Statistically significant improvement of spontaneous speech,	-

			Aphasia: Moderate			ANELT CETI	repetition, and naming (BNT, AAT) and clinically significant improvement in everyday language (ANELT) and communicative effectiveness (CETI) in the BOX group that was not found in CIAT group	
Woldag, et al. 2017	RCT	60	Age: 68.2 (SD 11.7) years TPO: 18.9 days	CIAT Conventional treatment group Conventional group and individual therapy	3 hours a day 10 working days 3 hours a day 10 working days Individual therapy 30mins 2 x a day and 1 hour group therapy 2 x a week =14 hours	AAT CAL	Statistically significant improvement in communicative activities (CAL) no between group differences were found.	-

TPO= Time post onset, CIAT= Constraint Induced Aphasia Therapy ILAT=Intensive Language Action Therapy CEI=Communicative Effectiveness Index AAT=Aachen Aphasia Test CAL=Communication Activity Log TT= Token Test BDAE= Boston Diagnostic Aphasia Examination BNT= Boston Naming Test NGA= Norwegian basic aphasia test VOST = Verb and Sentence Test PALPA = Psycholinguistic Assessments of Language Processing in Aphasia COAWT= Controlled Oral Word Association Test SFC= Semantic Fluency Test PPVT= Peabody Picture vocab test, VIT= Verb Inflection Test, WAB AQ Western Aphasia Battery Aphasia Quotient ACT= Action Communication Test ANELT = Amsterdam Nijmegen Everyday Language Test

Eight studies reported a statistically significant improvement in aphasia severity on the Western Aphasia Battery (WAB) Aphasia Quotient (58,71,147,158–162) and one study reported clinical but not statistical significance on this measure (160). Three studies report statistically significant language improvement on the Aachen Aphasia Test (77,163,164). Fifteen studies reported statistically significant improvement in naming ability on varied tests including the Boston Naming Test, Object and Action Naming Test, Object naming test of the Psycholinguistic Assessments of Language Processing in Aphasia and non-standardised naming tasks that included items treated in ILAT-based interventions and items not treated in ILAT-based interventions. Seven studies reported significant improvement on spontaneous speech as measured by the Aachen Aphasia Test. Four studies reported significant improvement in repetition as measured by the AAT and WAB and three studies reported improvements in language comprehension on the same measures. One study reported an improvement in the speed items were named and one study reported an improvement in the number of correct information units assessed during story retell. Five studies report an improvement in communicative function as assessed by the Communication Activities Log. One study reported an increase in quality of life as measured by the Stroke and Aphasia Quality of Life Scale. One study reported positive reports of ILAT-based intervention assessed by a self-report measure, this measure also showed that participants were divided in their opinions about the intensity of ILAT-based intervention with some preferring more hours per day and others less. 20 studies examined ILAT-based interventions in comparison with another intervention, using a different intensity or a variation of two ILAT-based interventions. Six of these 20 studies found no differences between the interventions being examined. Wilssens et al, 2005 found a semantic therapy called BOX achieved better language outcomes than the ILAT-based intervention (165) . Stahl et al, 2018 found higher intensity ILAT-based intervention beyond two hours a day did not provide additional benefit to participant outcomes (77). The remaining eleven studies found ILAT-based interventions achieved better language outcomes than the comparison therapies. Fourteen studies reported assessing for maintenance of intervention outcomes over varying time periods spanning one month to 12 months. The remaining sixteen studies reported no maintenance assessment.

3.4.3 Quality of reporting of ILAT-based interventions assessed by TIDieR

Included studies were assessed for completeness of describing how the intervention was delivered using the TIDieR checklist (149) for reporting interventions which is summarised in Table 10 All included studies provided a name for the intervention including CIAT, CIATplus, CIAT II, CILT, CILTplus and ILAT. All included studies provided some form of rationale or goal for the use of ILAT-based interventions as a treatment for aphasia however, there was variability in the reported rationale and goal of ILAT-based interventions. A more detailed examination of the rationale for ILAT-based

interventions reported in the included studies is summarised in Table 11 and will be discussed in more detail in 3.5.1 Mode of delivery.

Only two studies did not include details of the materials specifically the cards used for ILAT-based interventions. The procedures for delivering ILAT-based interventions were well described in all studies except Lucchese et al. (2017) study (144), and Stahl et al. (2017) study (166) however a reference to Difrancesco, Pulvermuller, and Mohr methods (2012) paper (57) was provided and for the Stalh et al. (2018) paper a reference to an earlier study from the same group (144) so an assumption that these procedures were followed could be made.

Table 10 Quality Assessment of intervention reporting in included studies using TIDieR

TIDieR items	Brief name	Rationale	Materials	Procedures	Provider	Mode of delivery	Type/Location of delivery	Dose/ intensity	Tailoring	Modifications	Fidelity assessed	Fidelity achieved	Total score
Attard, Rose & Lanyon, 2012	CIATplus	+	+	+	+	-	-	+	-	-	-	-	5/11
Berthier, et al. 2009	CIAT	+	+	+	+	+	-	+	+	-	-	-	6/11
Breier, et al. 2006	CILT	+	+	+	-	-	+	+	+	-	-	-	5/11
Carpenter & Cherney, 2015	CIAT	+	+	+	+	+	+	+	-	-	-	-	7/11
Ciccone, et al. 2015	CIAT	+	+	+	+	+	+	+	+	-	+	-	9/11
Difrancessco & Pulvermuller, 2012	ILAT	+	+	+	+	+	+	+	+	-	-	-	8/11
Faroqi-Shah & Virion, 2009	CILT	+	+	+	-	+	-	+	-	-	-	-	5/11
Johnson et al. 2014	CIAT II	+	+	+	-	+	-	+	+	+	+	-	8/11
Kirmess & Maher, 2010	CILT	+	+	+	-	-	+	+	+	-	+	-	7/11
Kristensen, et al. 2015	CIAT	+	+	+	+	+	+	+	+	-	-	-	8/11
Kurland, et al. 2016	CIAT	+	+	+	+	+	+	+	+	-	-	-	8/11
Kurland, et al. 2012	CILT	+	+	+	-	-	-	-	+	-	-	-	4/11
Kurland, Baldwin &Tauer, 2010	CILT	+	+	+	-	-	+	+	+	-	-	-	6/11
Lucchese, et al. 2017	ILAT	+	-	-	-	-	+	+	-	-	-	-	3/11
Macgregor, et al. 2015	ILAT	+	-	+	+	+	+	+	+	-	-	-	7/11
Maher, et al. 2006	CILT	+	+	+	+	+	+	+	+	+	-	-	9/11
Meinzer, et, al, 2005	CIAT CIATplus	+	+	+	-	+	+	+	+	-	-	-	7/11
Meinzer, et al. 2007	CIAT	+	+	+	+	+	+	+	+	+	-	-	9/11
Mohr, et al. 2016	ILAT	+	+	+	-	+	-	+	-	-	-	-	5/11
Mozeiko, et al. 2018	CILT	+	+	+	-	+	-	+	+	-	-	-	6/11
Pulvermuller, et al. 2001	CIAT	+	+	+	-	+	-	+	+	-	-	-	6/11
Pulvermuller, et al. 2005	CIAT	+	+	+	+	+	-	+	+	-	-	-	7/11
Rose, et al. 2013	CILTplus	+	+	+	+	+	+	+	+	-	+	+	10/11
Sickert, et al. 2014	CIAT	+	+	+	-	+	-	+	+	-	-	-	6/11
Stalh, et al. 2016	ILAT	+	+	+	-	+	+	+	+	-	-	-	7/11
Stalh, et al. 2017	ILAT	+	+	+	-	+	+	+	+	-	-	-	7/11
Stahl, et al. 2018	ILAT	+	+	+	-	-	-	+	+	-	-	-	5/11
Szaflarski, et al. 2015	CIAT	+	+	+	-	+	-	+	+	-	-	-	6/11
Wilssens, et al. 2015	CIAT	+	+	+	+	+	+	+	+	-	-	-	8/11
Woldag, et al. 2017	CIAT	+	+	+	+	+	+	+	+	-	-	-	8/11
Components met		30/30	28/30	29/30	14/30	25/30	18/30	29/30	25/30	3/30	4/30	1/30	

Much less well reported was the provider of ILAT-based interventions. Fourteen studies reported who delivered ILAT-based interventions which included trained SLTs, SLT students, neuropsychologists and one study reported laypersons who were caregivers to the participants in the study (122). Four studies did not report who provided ILAT-based interventions (114,144,152,167). The ten remaining studies provided either a generalised title such as therapist or clinician without specifying training or experience (27,77,112,151,158,163,164,168–170) and two studies stated the authors completed the intervention (58,171). Even where training was reported, very little detail was offered as to what the training entailed. Meinzer et al. (2007) reported the most detail of the training reporting that a two hour seminar containing details of ILAT principles, procedures, materials and approaches to eliciting spoken language were delivered to laypersons prior to delivering ILAT-based interventions (122). Eighteen studies reported the location and location type, these included hospital-based outpatient clinics, university clinics and inpatient rehabilitation centres and hospitals.

All but one study described the dose and intensity of ILAT-based intervention delivery. Kurland et al (2012) (152) provided only the description a 'two week period', failing to report the number of hours a day or the total number of therapy hours delivered.

Twenty-four studies reported that materials and individualised rules were used to tailor ILAT-based interventions to the individual participant. Three studies reported if any modifications were made to the procedures during the study. Four studies reported fidelity testing was completed. Two of these studies did not report the result of the fidelity testing (147,167). Johnson et al (2014) reported that one of the four participants did not adhere to the home practice and did not perform all tasks in the intervention in the clinic (168). Rose and colleagues rated treatment fidelity using independent raters and recorded sessions of ILAT-based intervention and reported 100% adherence to the treatment protocol (58).

Table 11 Included studies and components of ILAT-based interventions categorised by the principles of experience dependent plasticity (#numbers refer to Table 1)

			Components targeting salience (#g)		**Intensity (#d,e)**	**Components targeting specificity (#c)**		**Use-it-and-improve-it (#b)**		**Components targeting use -it-or-lose -it (#a)**			**No. Components**
Study	**Name**	**Group**	**Language Action Embedding**	**Behavioural relevance**	**Massed Practice**	**Feedback**	**Prompts**	**Shaping**	**Tailoring**	**Constraint/ focusing**	**Barriers**	**Learned non-use**	
Attard, Rose & Lanyon, 2012	CIATplus	+	-	-	+	-	Phonemic, Repetition	-	NR	+	+	-	5/11
Berthier, et al. 2009	CIAT	+	+	-	+	+	NR	+	+	+	+	+	9/11
Breier, et al. 2006	CILT	+	-	-	+	+	Semantic , Phonemic Repetition	+	+	+	+	-	8/11
Carpenter and Cherney, 2015	CIAT	+	-	-	+	-	Phonemic, Semantic	-	-	+	+	-	4/11
Ciccone, et al. 2015	CIAT	+	-	-	+	+	Unspecified cues	+	+	+	+	+	9/11
Difrancessco &Pulvermuller 2012	ILAT	+	+	+	+	+	Clarification questions	+	+	+	+	+	11/11
Faroqi-Shah & Virion, 2009	CILT	+	-	-	+	-	General prompts	+	+	+	+	-	7/11
Johnson et al. 2014	CIAT II	+	-	-	-	+	Prompted by caregiver to avoid errors	+	+	+	+	+	8/11
Kirmess & Maher, 2010	CILT	+/-	+	-	+	NR	NR	+	+	+	+	+	8/11
Kristensen, et al. 2015	CIAT	+	+	+	+	NR	NR	+	NR	+	+	+	8/11
Kurland, et al. 2016	CIAT	+	+	+	+	+	Associative cuing, cloze sentences, phonemic, written, repetition	+	+	+	+	+	11/11
Kurland, et al. 2012	CIAT	NR	+	+	+	+	NR	+	+	+	+	+	9/11
Kurland, Baldwin & Tauer, 2010	CILT	NR	-	-	+	+	NR	+	+	+	+	-	6/11
Lucchese, et al. 2017	ILAT	+	-	-	-	+	NR	-	+	-	+	-	4/11
MacGregor, et al. 2015	ILAT	+	+	+	+	NR	NR	-	NR	+	NR	-	5/11
Maher, et al. 2006	CILT	+	+	-	+	+	Phonemic, Semantic, Repetition	+	+	+	+	-	7/11
Mienzer, et al. 2005	CIAT CIATplus	+ +/-	-	-	+	NR	NR	+	- +	+	+	-	5/11 6/11
Meinzer, Streiftau & Rockstroh, 2007	CIAT	+	-	-	+	+	Phonemic, Semantic	+	+	-	+	-	6/11

Mohr, et al. 2016	ILAT (CIAT)	+	-	+	+	NR	NR	-	NR	+	+	-	5/11
Mozeiko, et al. 2018	CILT	+	-	-	+	NR	Phonemic, Semantic, Modelling , Error reduction	+	+	+	-	-	6/11
Pulvermuller, et al. 2001	CIAT	+	+	+	+	+	Reinforcement contingencies	+	+	+	+	+	11/11
Pulvermuller, et al. 2005	CIAT	+	+	+	+	+	NR	-	+	+	+	-	8/11
Rose, et al. 2013	CILTPlus	+	-	+	+	+	Phonemic, Written, Repetition	+	+	+	+	-	9/11
Sickert, et al. 2014	CIAT	+	-	-	+	+	Cueing as necessary	+	+	+	+	-	8/11
Stalh, et al. 2016	ILAT	+	+	+	+	+	Cueing strategies	-	+	-	+	-	8/11
Stalh, et al. 2017	ILAT	+	+	+	+	NR	NR	NR	NR	NR	NR	-	4/11
Stalh, et al. 2018	ILAT	+	+	-	+	+	Modelling and embedded semantic cues (explicitly not phonemic, semantic or repetition)	+	+	-	+	-	8/11
Szaflarski, et al. 2015	CIAT	+	-	+	+	+	Repetition to verbal reminder	+	+	+	NR	+	9/11
Wilssens, et al. 2015	CIAT	+	-	+	+	NR	Reinforcement contingencies	+	+	+	+	-	8/11
Woldag, et al. 2016	CIAT	+	-	-	+	+	Cueing as necessary	+	+	+	+	-	8/11

3.5 Narrative synthesis of included studies

The aim of the narrative review was to examine how ILAT-based interventions have been reported in the literature and determine which research studies were concordant with the current theory of ILAT and to inform the delivery of ILAT in this thesis. Many of the included studies did not report using all the components of ILAT, and the definition, practical use and understanding of the components differed across the studies. Table 11 shows the results of ILAT components reported in the included studies. Each component is discussed in turn.

3.5.1 Mode of delivery

Studies reported delivering ILAT-based interventions as both a group and individual intervention. Two studies did not report how ILAT-based interventions were delivered however both were single participant designs and perhaps the intervention was provided individually with a facilitator (114,152). The remaining studies reported treating participants in groups of two to four in keeping with the originators methods (57) see Table 11.

3.5.2 Components targeting salience

Eighteen of the 31 included studies did not discuss salience or behavioural relevance as a key rationale underpinning ILAT-based interventions. However, in the discussion of the methods all studies reported using language action games (LAG's) that are designed to mimic everyday conversational exchange. So, whilst the majority of studies did not report the importance of salience or behavioural relevance as an underlying principle of ILAT based interventions, all studies adhered to this through the use of the LAG. Earlier studies of ILAT BASED INTERVENTIONS reported prior to 2012, described only using one type of LAG, the request game. Whereas, those studies reported after 2012 reported using a planning game that encourages more diverse speech acts.

3.5.2.1 Language action embedding

Whilst only 13 of the included studies referenced language action embedding in describing ILAT based interventions, all studies required participants to complete LAG's, with eight studies mentioning using both requesting and planning games. All studies reported participants explicitly accepting or declining a request/plan and physically exchanging cards as part of ILAT based interventions, fulfilling the requirement to perform the physical action of the exchange and supporting the underlying principle of language action embedding.

3.5.3 Components targeting repetition and intensity

There is a great deal of variability in the intensity and overall dose of ILAT based interventions reported in the literature (see Table 11). The overall dose and the amount of practice per day varied

in the included studies from 45 minutes a day up to 4 hours a day and from as little as six days to as many as ten weeks for overall dose of ten to 60 hours. Pulvermuller et al. (2001), initially reported a schedule of three hours a day for ten days resulting in 30 hours of ILAT based intervention (112); Fifteen (50%) of the included studies followed this same intensively delivered massed dose. Four studies specifically examined the effectiveness of massed and intensively delivered ILAT based intervention with differing, overall dose, intensity and massed delivery and with differing comparison methods to shed light on the optimal treatment schedule:

Pulvermuller et al (2001), in the first published study of ILAT based interventions, compared intensive treatment delivered three hours a day for ten days to distributed 'conventional therapy' delivered over four weeks. The dose of 30-35 hours remained consistent between groups. The authors reported significant improvement in the ILAT based intervention group on language assessment and an increase in the amount of everyday language use that significantly differed from the control group. Pulvermuller et al. (2001) concluded that the massed practice appeared to have a positive effect on communication for people with aphasia (112).

Mozeiko et al (2018), compared a low intensity 30 hours delivered over ten weeks to the traditional dose of 30 hours over two weeks with the explicit goal of assessing the impact of intensity in ILAT based interventions. The authors reported a positive gain in all patients however the changes to standardised testing (WAB-R AQ) were more consistently positive for those participants who received intensive ILAT based intervention. Improvements on the CADL -2 were reported and these improvements were maintained only by those treated in the intensive ILAT based condition. However, the authors warn that caution is required in interpreting the results due to the uncontrolled design and small number of participants (n=6) (see Table 9 (172)).

Most recently, Stahl et al (2018), compared a lower intensity ILAT based intervention of two hours a day (total of 20 hours) over two weeks to a high intensity ILAT based intervention delivered at four hours a day (total of 48 hours) over two weeks. The authors report no additional benefit of the higher intensity above that of the lower intensity ILAT based intervention stating a decline in attention and fatigue may reduce the effectiveness of additional hours of ILAT based intervention. Stahl et al (2018), do recognise that two hours a day is still significantly more intervention than is generally delivered to people with aphasia and would be considered an intensive, massed intervention. The authors conclude a minimum dose of between five to ten hours per week is required to achieve progress in communication for people with aphasia (28,82).

Overall, the original schedule of 30 hours (three hours a day for ten days) is the most well researched schedule. Thus, it was used for this research.

3.5.4 Components targeting specificity

3.5.4.1 Prompts and feedback

There was a diverse range of techniques described in the studies, ranging from errorless learning techniques of giving participants a model to repeat, providing traditional SLT prompts, to not providing any kind of prompts at all:

Six studies did not report if any feedback or prompts were given to participants to encourage continued participation in therapy (160,166,167,173,174). Three studies reported that no feedback was given but did detail some prompting that was given to overcome communication breakdown (153,158,171). Five studies stated feedback was given but did not report any prompting was used throughout the intervention (114,144,146,152,159) The remaining studies reported providing some form of feedback about participant performance and a wide variety of prompts ranging from unspecified prompts, general prompts or prompts as necessary (147,154,158,166,175) to traditional SLT prompts including phonemic (first sound), semantic (providing a clue) and repetition. One study reported using modelling and error-reduction methods of providing the participant the desired language to repeat following errorless learning methods (172). A further two studies reported using reinforcement contingencies defined as requiring participants to comply with different constraints of politeness, carrier phrases and level of linguistic complexity through which feedback on performance was given. However, there was no mention of how communication breakdown was addressed by clinicians in these two studies (112,165).

3.5.5 Components targeting 'use-it-and-improve-it'

3.5.5.1 Shaping

Eight of the included studies didn't discuss or report the use of shaping in the delivery of ILAT based interventions (144,146,153,154,171,173,174). Those that did report shaping simply stated as above that this was achieved through materials or rules. Two studies reported specific criteria for progressing to a more complex level of communication with explicit direction to produce certain syntactic structures for example embedded phrases or producing adjectives before progressing to the more complex materials or rules (147,158).

3.5.5.2 Tailoring

The majority of studies reported tailoring rules and shaping contingencies for participants during ILAT based interventions. Carpenter and Cherney (2015), reported following a specific protocol for all

participants regardless of severity of aphasia (153). Faroqi-Shah and Virion (2009), reported following a six-level hierarchy for progressing through ILAT based intervention tasks moving participants between levels when one level was achieved twice. Therefore, allowing a degree of tailoring within a strict protocol of performance requirements (147). Five studies did not report any tailoring of ILAT based interventions (153,160,166,171,173,174).

3.5.6 Components targeting 'use-it-or-lose-it'/learned non-use

3.5.6.1 Learned non-use

Only ten of the 31 included studies discuss the underlying principle of learned non-use as a rationale for utilising ILAT based interventions (57,112,147,152,159,160,164,167,168,176). However, again the procedures for ILAT based interventions encourage participants to use the neglected neural networks through the materials, constraint and shaping and therefore if the methods for practical delivery are adhered to then the component of use-it-or-lose-it is maintained within the delivery of ILAT based interventions. Only one study failed to report the use of any of the components of 'use-it-or-lose-it' and 'use-it-and-improve-it' however a reference to Difrancesco, Pulvermuller and Mohr (2012) (57) was cited therefore it may be possible to assume that these procedures were followed (177).

3.5.6.2 Constraint/focusing and barriers

Seventeen studies reported using constraint of verbal communication however the definition of constraint varied between studies. Five of the included studies did not report or discuss constraint in the description of the ILAT based intervention (77,122,144,163,166). Four of these studies were published after the 2012 methods paper (17,34–36) when the procedures for constraint were re-defined and relabelled focusing, with only one paper prior to 2012 (122). The definition of constraint varied from the complete prevention of non-verbal communication with one paper asking participants to sit on their hands, to the reinterpreted version of allowing non-verbal communication as an aid in producing spoken communication but preventing non-verbal communication from replacing spoken communication. However, it was consistently reported that participants were required to produce verbal communication to successfully complete ILAT based interventions.

One study did not use barriers during ILAT based interventions (151) and three studies did not report barrier use (164,166,173). The remaining studies reported using barriers, therefore, reinforcing the need for participants to use verbal language when completing ILAT based interventions.

3.6 Conclusions of part 1

The overarching aim of this chapter was to describe ILAT, its underlying theory, mode of action, its key elements and described the faithful delivery of ILAT for this research. The first review mapped the development of ILAT and its previous version CIAT/CILT detailing the programme theory of ILAT. The second review examined how ILAT based interventions has been reported in the literature and determined if and how components of ILAT have been described.

Through the review of key theoretical literature, discussion with the originator of ILAT and observation of ILAT being delivered, five essential categories of components of ILAT have been identified that target the principles of experience dependent learning that are believed to trigger Hebbian learning in the treatment of aphasia:

(6) salience (component: language action embedding; actions: card exchange, LAG's and the group context);
(7) intensity and repetition (component: massed practice, action: ILAT delivered for 30 hours over ten days);
(8) specificity (components: prompts and feedback, actions: using clarification questions and reinforcement contingencies);
(9) use-it-and-improve-it (components: shaping and tailoring actions: reinforcement contingencies and stimulus materials); and,
(10) use-it-or-lose-it (component: constraint/focusing, actions: barriers, reinforcement contingencies and stimulus cards)

Overall, the quality of the reporting in the 31 studies of ILAT at the level of the TIDieR assessment was fairly consistent with modification and fidelity most poorly reported. Only three studies reported modification, only three studies reported assessing fidelity and only one study reported whether fidelity was achieved, despite fidelity being a criteria since the 1996 CONSORT statement for better reporting of randomised control trials (178), which was published prior to all the included studies. Further since 2012 fidelity has been a required item in the Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare (CReDECI) (179).

In the 31 studies included in the narrative review of ILAT there was substantial variability in the use and definition of these five essential components of ILAT. Only three studies reported using all the components of ILAT and within these studies there was variability in the practical delivery of the components. Massed practice, shaping, constraint/focusing and barrier use were most commonly delivered components of ILAT.

Given the variability of use, understanding and reporting of the methods used to deliver ILAT the interpretation of how to deliver ILAT appears to vary considerably. Quality of intervention reporting according to Tidier also varied with little attention paid to fidelity measurement and modifications. On the whole, the intervention often wasn't sufficiently described for replication in further research studies or for implementation into clinical practice thus limiting the usefulness of these studies in developing the treatment protocol for the research in this thesis. Therefore it is necessary to develop a well described ILAT procedure to be evaluated in this thesis, based on the essential components, and the useful description of some delivery methods described in the review of previous studies, which included: the need for massed practice with a minimum dose of five hours a week (77); planning LAGs which encouraged more varied speech acts to be practised (57); and, delivery of ILAT with volunteers that requires further evaluation (122).

This narrative review aimed to fully examine the literature pertaining to ILAT and its predecessors CILT and CIAT. The inclusion of the varying research designs from case study to randomised controlled trial allowed the full range of literature to be examined and compared. Therefore, allowing a clear understanding of how ILAT has been reported in the literature. A weakness of this review is that a single reviewer selected the included studies and extracted all data.

Part two of this chapter describes the development of the treatment manual, description of ILAT using TIDieR and the development of a logic model and program theory.

Part 2: Development of ILAT delivered by assistants/volunteers

Whilst the components of ILAT and their practical delivery were not modified during this research; the efficient method of delivering ILAT in the NHS; using assistants/volunteers and the required operationalisation, training and supervision and methods of delivering ILAT were developed through an iterative development process. The aim of part 2 was to describe the development of ILAT delivered by assistants/volunteers for use in a pilot RCT. The specific objectives were to:

- develop a program theory and logic model for assistant/volunteer delivered ILAT within the NHS; and,
- specify an ILAT treatment protocol for the NHS through the description of ILAT using TIDieR, and through the development of a treatment manual including materials and an assistant/volunteer training program.

3.7 Methods

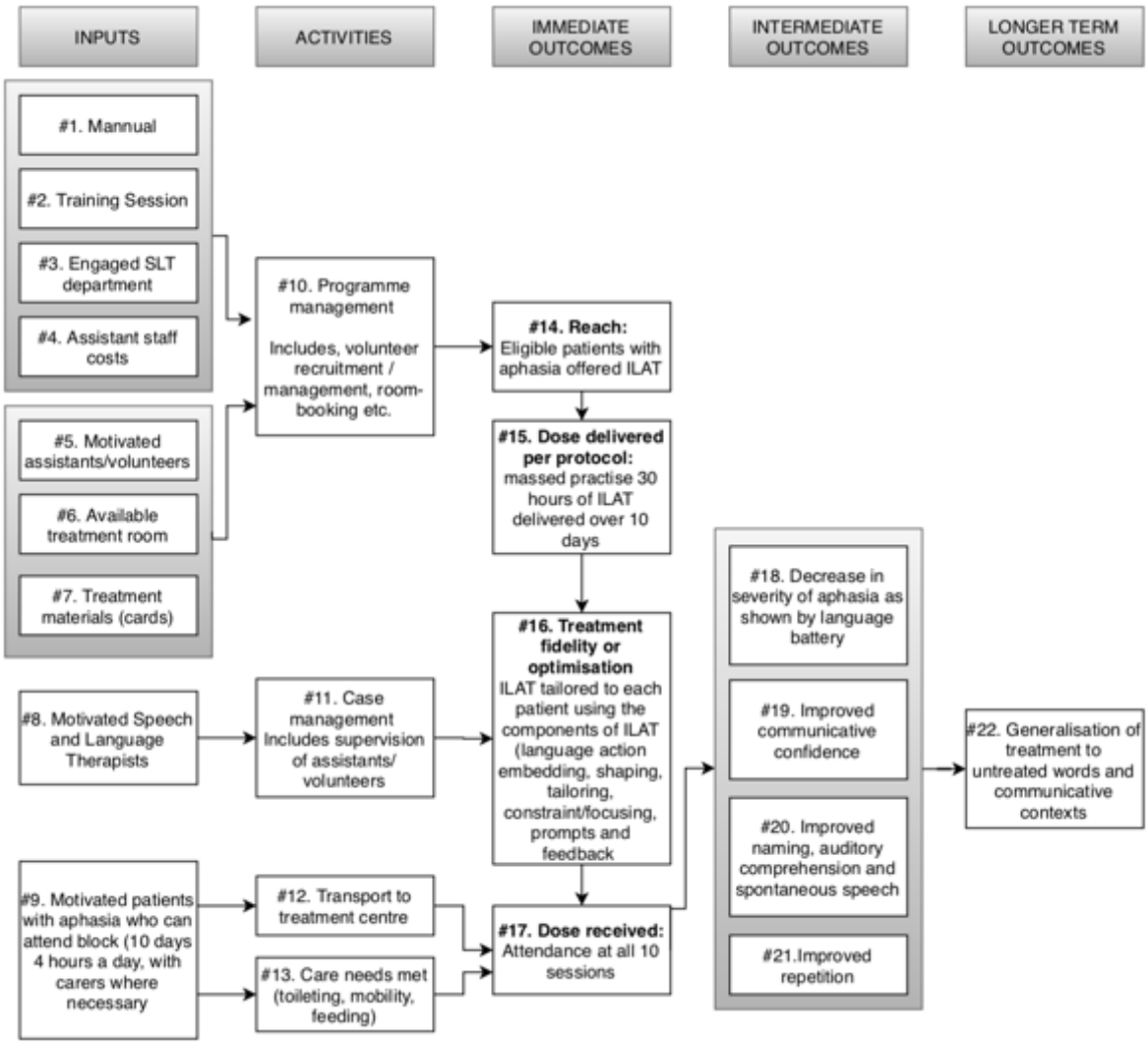
Methods comprised the development of the programme theory and logic model; the development of the SLT and assistant/volunteer manual and materials required to deliver ILAT and the training and supervision packages; the description of ILAT using TIDieR; and finally a consultation with key stakeholders that resulted in the first iteration of ILAT delivered by assistants/volunteers that was piloted in ILAT course one.

3.8 Development of the logic model

Logic models are a tool that provides a visual representation using a series of boxes and arrows that represent the resources, immediate and long term outcomes of a program theory (180). A logic model (see Figure 9) was developed that described the perceived requirements for delivering ILAT to achieve it intended outcomes by faithfully delivering the components of ILAT (language action embedding, massed practise, shaping and tailoring, prompts and feedback, constraint/focusing see

Figure 7 7 in section 3.2). This was based on observations of ILAT delivery at the originator's clinic in Berlin, my own clinical experiences of delivering ILAT in the NHS, and both the theoretical literature and narrative review of how ILAT has been delivered in evaluations to date. The logic model describes the resources required to deliver ILAT within the NHS and the immediate, intermediate and longer term outcomes and outlines the links and assumptions between resources (inputs), activities, intermediate outcomes and long term outcomes. Any missing or unsatisfactory inputs, activities or immediate outcomes may impact the intermediate and longer term outcomes. The initial logic model was designed by the research SLT and an iterative evaluation of the procedures was completed after each ILAT course was delivered and the problems, solutions and success of these solutions were assessed (see section 4.6.6 Fidelity assessment of ILAT for methods, see section 6.3 Fidelity Assessment Results and 6.5 Approaches taken to modify ILAT to improve feasibility and fidelity of delivery, and acceptability to facilitators and patients).

Figure 9 ILAT Logic Model



3.8.1 Inputs

Inputs are the physical resources, including staff and participants, that are required to deliver assistant/volunteer delivered ILAT. The development of the manual and training are described in section 3.10 Development of procedures for assistant/volunteer delivered ILAT. In terms of delivering this package of ILAT there needs to be engagement from the SLT department to ensure participants are referred and resources such as assistant staff are provided. Assistant time needs to be sourced to allow them to be released from regular duties or work additional hours to deliver the 30 hours of ILAT. Assistants who are motivated and willing to participate need to be identified. Treatment rooms need to be identified and treatment materials prepared for use (including the tailoring to participant interest). A motivated, trained SLT is required to identify patients with aphasia and complete the case management and program management. The final input is to identify motivated patients with aphasia who are able to attend a course of ILAT. Motivation can be assumed through willingness to participate and will be assessed through attendance during ILAT course.

3.8.2 Activities

Once the inputs or resources are available activities need to be completed that allow the outcome, delivering and receiving the intervention, to be achieved. Programme management includes, recruiting volunteers and ensuring compliance with NHS trust policies, providing training to assistants/volunteers, setting the dates for the ILAT course, booking treatment rooms etcetera. The programme management includes all those things that need setting up to start running a ILAT course including delivering training and supervision to assistants/volunteers to ensure the components of ILAT are delivered (language action embedding, shaping, tailoring, prompts and feedback, massed practice, constraint/focusing). Case management includes assessing the severity of aphasia of all patients and collecting information about topics of interest to allow the tailoring of ILAT to be completed including setting the rules for individual participants and producing any treatment materials for patient preferred topics. Case management ensures that ILAT is set up in such a way that patients will be operating at the outer limit of their communicative ability and maximises the behavioural relevance of ILAT through the tailoring of materials. Finally, it is important to consider the care needs including transport needs of patients as if these can't be met then no matter how motivated or available patients are they will be unable to receive the intervention if they are unable to get to the treatment room or stay for the course because of care needs.

3.8.3 Immediate Outcomes

Once the activities are completed the immediate outcomes are to deliver ILAT (dose) to eligible patients (reach) so that the dose of ILAT is received (dose received). The dose for this study will be 30 hours across ten working days, in line with Pulvermuller et al (2001) and confirmed through the

literature review (see section 3.5.3 Components targeting repetition and intensity(181)). The 5 essential components of ILAT; language action embedding, massed practice, prompts and feedback, shaping and tailoring and constraint/focusing will be delivered to ensure ILAT is delivered with fidelity. It is important to consider the delivery of the intervention as a separate entity to receiving the intervention, as separate issues may impact these processes. For example, the 30 hours of ILAT may be delivered but a patient may be unable to attend a session. Therefore, the intervention was delivered but not received.

3.8.4 Intermediate and longer term outcomes

If all the inputs, activities and immediate outcomes are all completed then the intermediate outcomes which reflect the clinical outcomes should be achieved. The outcomes of ILAT were identified through the literature review and assess different aspects of communication that are affected by aphasia. The intermediate outcomes are decreased aphasia severity as assessed by language battery, increase in communicative confidence, improved naming of objects, improved auditory comprehension, improved spontaneous speech and improved repetition. These outcomes are discrete skills that comprise communication and are proposed to generalise to untreated words and communicative contexts, in other words achieving the intermediate outcomes is proposed to improve the ability to have conversations in everyday life.

3.9 Description of ILAT using TIDieR

The TIDieR checklist for complex intervention reporting was used to clearly define ILAT and its delivery in this research (see Table 12). A description of each element will follow to provide the exact definition and delivery of ILAT for this research.

3.9.1 Intervention Name

For this research the intervention will be referred to as Intensive Language Action Therapy as this is the preferred name of this intervention by the originator. ILAT encompasses the concepts of the intervention's intensive delivery and the language action components (57).

3.9.2 Rationale, theory and goal of ILAT

The five essential components that provide the theoretical underpinning and inform the practical delivery of ILAT (See Figure 7 and section 3.2 Intensive Language Action Therapy: the theory, for discussion of each component) were maintained and operationalised into the first iteration of the manual and treatment procedures for ILAT in this research. The underlying rationale and theory of ILAT is that people with aphasia suffer from learned non-use in that they avoid speaking or use inexact or stereotypical language to compensate for damaged neural networks. ILAT aims to activate

diverse neural networks including those containing information for language as well as related motor and sensory neural networks to strengthen the entire neural network through a process of Hebbian learning (see 3.2 Intensive Language Action Therapy: the theory, for a full discussion of underlying principles). The goal of ILAT is to improve the ability of people with aphasia to have conversations through the strengthening and repair of neural networks and through the teaching of techniques that overcome breakdown in communication.

3.9.3 ILAT materials

ILAT uses picture cards to stimulate participant's language output. Difrancesco, Pulvermuller & Mohr (2012) (138) have compiled an English language set of cards which were used for this study. In addition, personalised picture cards were created that reflect the interests and topics of conversation of each participant identified during baseline assessment and throughout ILAT courses (See Appendix 9 ILAT Manual and Assistant/volunteer Handbook for further details of materials). The cards used for the language action games are provided in packs. Each pack contains pairs of cards. There are six categories of card: Frequent words, depicting common everyday objects; Minimal pairs, depicting objects that differ by only one sound for example glass and grass; Semantic Categories, such as food, animals, clothing; Multi Feature, depicting objects that vary in colour, size or number; Spatial relationships, depicting objects that are in spatial relationships such as in, on, under; and Action, depicting actions such as brushing teeth or eating at a restaurant.

Tabletop barriers will be used to prevent participants from gesturing to other participants or from seeing or showing cards before a match is made through spoken communication.

The assistants/volunteers used a Daily intervention log (DIL) to record the progress of each participant (see Appendix 8 for detail). The DIL was developed out of methods reported in Difrancesco, Pulvermuller and Mohr, (138) and through observations and discussions with the SLT working in the originator's clinic in Berlin. The DIL is a scoring sheet that will be completed for each turn taken during language action games across several parameters. These parameters are: rule complexity, to rate the complexity of the turn such as a two word phrase or a complex grammatical sentence; rule components such as using a carrier phrase or politeness term; appropriateness, which was a four point rating scale from zero meaning not functional to three fully functional; a space to record what prompts were used and how many and an additional comments section. These parameters recorded on the DIL will be used to direct the structure for supervision provided by the research SLT and record the tailored rules, shaping and focusing instructions for each participant in the subsequent ILAT sessions (see 3.10.2 Development of the Daily Intervention Log (DIL) for details

of the development of the DIL). Appendix 8 shows version one of the DIL that was piloted in the first ILAT course delivered in the research project.

3.9.4 ILAT procedures

Difrancesco, Pulvermuller and Mohr, (2012) state that rules and materials of ILAT must encourage each participant to work at the outer limit of their communication competence (138). In order to achieve this a Speech and Language Therapist will complete an assessment of the patient's language to determine severity of aphasia and identify participant interests to allow the tailoring of the ILAT complexity/component rules and materials so that ILAT supported participants to work at the outer limit of their communication competence.

During the therapy participants play Language Action Games (LAGs). LAGs are card exchange games like Old Maid and clarification questioning that is similar to Guess Who? Each participant is dealt several cards from a card set (see section 3.9.3 ILAT materials for details of card sets) and then attempt to find matching pairs of cards by requesting them from other participants. Participants are required to speak clearly and correctly to make sure they are given the correctly matching card. Each participant requests a card in turn until all the cards are matched. Each LAG will aim to take approximately 1 hour to complete. However, if the LAG is completed in less than one hour another round of cards is dealt to continue the LAG until the hour is complete following procedures observed in the originator's clinic.

The cards are dealt out evenly from the chosen set, ensuring no participant has a matching set in their own cards. Then in turn each participant makes requests to find a match to their card. If participant A asks participant B and he did not have the card, participant A asks each participant in turn until the card was found. If participant A asks participant B but there was a mismatch and participant B presents the wrong card due to a miscommunication; then participant A's turn ends. Then the next participant makes a request and so on as each participant takes a turn following the methods described in Difrancesco, Pulvermuller and Mohr's methods paper (57).

Two facilitators, assistant/volunteer, are allocated to each ILAT session. One facilitator participates in the therapy, providing a model for participants to follow and asking clarification questions where communication breakdown occurs. The second facilitator ensures the session runs smoothly providing prompts to participants when communication breakdown was unresolved by clarification questions, following the methods described in Difrancesco, Pulvermuller and Mohr's methods paper (57). The second facilitator also completes a record of communication exchanges on the DIL to enable accurate feedback during daily supervision sessions conducted by the research SLT. The

decision to divide the tasks of scoring the DIL and facilitating the group between the two assistants/volunteers was in line with the recommendations of Difrancesco, Pulvermuller and Mohr's methods paper and observations of ILAT being delivered in the originators clinic (57).

Supervision is provided by the research SLT who monitors the progress of each participant through daily supervision sessions. Supervision is provided daily at the end of each ILAT session. However, ad hoc support and supervision is available from the research SLT if the facilitators require support either over the phone or in person as the research SLT will be on site but in another location. The goal of supervision sessions is to further modify the individual complexity/component rules and materials so that each participant progresses through ILAT sessions as appropriate. A guideline of the following criteria will assist the research SLT in determining how to progress patients through ILAT materials and complexity/component rules. Participants achieve:

- 80% compliance on complexity and component rules;
- a score of 2-3 on appropriateness ratings for 80% of communication exchanges;
- less than 3 clarification questions and no prompts per turn.

This criteria was informed by the research SLTs previous clinical experience of delivering ILAT and the narrative review of the ILAT literature (151).

3.9.5 Intervention providers

Facilitators will be therapy assistants/volunteers as this method had been reported successfully in the literature (122) and the research SLT had experience of delivering ILAT with assistants in clinical practice. Assistants/volunteers will complete training into the delivery of ILAT no longer than 2 weeks prior to facilitating an ILAT course, to ensure the recency of the training, and also limit the risk of assistant/volunteer dropout prior to delivering an ILAT course. Facilitators will receive a local induction to ensure awareness of supervision structure, facilities, local area and emergency procedures. Assistants will be recruited from the SLT department however it was not required that they have experience of working with people with aphasia as this allows the pool of assistants for inclusion to be larger, as physiotherapy, occupational therapy, speech and language therapy assistants as well as multi-disciplinary assistants were eligible to participate to ensure enough assistant time could be recruited to complete the ILAT courses.

Supervision, program management and training is provided by the research SLT who has experience supervising assistants/volunteers. The research SLT also had experience of delivering ILAT and supervising other SLTs and assistants to deliver ILAT.

3.9.6 Mode of delivery

ILAT will be provided face-to-face in a group of two to four participants with two facilitators, either assistants or volunteers

3.9.7 Location and infrastructure

ILAT will be provided in two general NHS hospitals. Treatment rooms will be sourced in the outpatient department and stroke unit that have access to both kitchen and toilet facilitates. Room requirements are; space enough for four people to sit around a small square table, two other seats for facilitators and space for facilitators to store and sort card sets for LAGs. The research SLT will be available in another room on site or over the phone however, the SLT department and stroke unit SLTs will be close to hand should an urgent need arise.

3.9.8 Dose and intensity

Participants will attend an ILAT course for four hours a day for ten working days. Each day consists of three hours of therapy and one hour of refreshment breaks for a total dose of 30 hours of ILAT in line with the intensity and massed practice identified through the narrative review.

3.9.9 Tailoring

Materials will be tailored to participant interest and severity of aphasia. Each participant will receive an individually tailored plan designed and managed by the research SLT, indicating the complexity and component rules and prompting required for that individual participant. The individual plans will be reviewed each day by the research SLT and updated as necessary (see example in Appendix 8).

3.9.10 Modification

In this research there was no intention of modifying the delivery of ILAT itself. Every effort will be made to maintain the fidelity of ILAT in line with ILAT as described in Section 3.9 Description of ILAT using TIDieR. What will be developed, through an iterative evaluation of the procedures, is the efficient method of assistant/volunteer delivered ILAT. Thus, procedures, manual, training and the supervision package are the focus of the intervention development (see chapter six for results of this process).

3.9.11 How well

An iterative process of fidelity assessment was used to ensure ILAT was delivered as intended. The iterative process allowed the intervention procedures to be enhanced between each delivery of ILAT to improve fidelity and the development of the training and therapy manual. The specific aims of the fidelity assessment were to assess:

- the adherence to the treatment manual and training and the faithfulness of the delivery of ILAT by therapy assistants/volunteers;

  2) the completeness of the data collected on the Daily Intervention Log;

  3) the accuracy of facilitators completing the Daily Intervention Log;

  4) the amount of intervention delivered and received; and,

  5) the participants and assistants/volunteers understanding and perceptions of ILAT including whether skills learned in ILAT impacted every day conversations.

See section 4.6.6 Fidelity assessment of ILAT for the full details of this process.

Table 12 TIDieR table defining ILAT for the research in this thesis

TIDieR item	**ILAT description**	
Brief name		Intensive Language Action Therapy (ILAT)
Why ?		There are 5 essential components that provide the theoretical underpinning and inform the practical delivery of ILAT; 1. Language action embedding 2. Intensive massed practice 3. Prompts and feedback 4. Shaping and Tailoring 5. Focusing/constraint The components attempt to activate the proposed underlying mechanism of action, Hebbian learning. (See section 3.2 Intensive Language Action Therapy: the theory for detailed discussion of each component, see section 3.8 Development of the logic model for practical details of delivery in this research)
What?	Materials	Picture cards following Difrancesco, Pulvermuller and Mohr (57) (Appendix 9) Table top barriers Daily intervention log (see section 3.10.2 Development of the Daily Intervention Log (DIL) and Appendix 8) Assistant/volunteer ILAT manual SLT supervision of ILAT manual Training package for assistants/volunteers
	Procedures	Facilitators play LAGs with participants, using clarification questions and prompts and feedback (see Appendix 9). One facilitator scores the DIL The research SLT provides daily supervision progressing participants through the treatment following the predetermined criteria (see section 3.9.4 pg. 92)
Who provided?		Facilitators are therapy Assistants/volunteers who completed training into the delivery of ILAT no longer than 2 weeks prior to delivering an ILAT course. Daily supervision and training is provided by a senior SLT who had experience with ILAT. 2 facilitators are allocated to each ILAT session.
How?		ILAT is provided face to face in groups of 2-4
Where?		Outpatient department in two NHS General Hospitals
When and How much?		30 hours provided 3 hours a day for 10 working days
Tailoring?		Materials and focusing rules are tailored to participant interest and communication capabilities (see section 3.5.5.2 For details)
Modifications?		The intervention will be iteratively modified based upon: field notes; attendance record; fidelity assessment and semi-structured interviews with assistants/volunteers and participants; to maintain clinical data integrity and treatment fidelity (See Chapter 6 for details)
How well?		An iterative process of fidelity evaluation was used see section 4.6.6 Fidelity assessment of ILAT

3.10 Development of procedures for assistant/volunteer delivered ILAT

Following the development of the programme theory and logic model and fully describing ILAT using TIDieR an ILAT therapy manual, treatment materials and training programme were developed using a consultative process. Key stakeholders were identified and are described in Table 13.

Thirteen key stakeholders were identified and approached to discuss the contents of the ILAT manual/ handbook (see Table 13). It was determined that there needed to be a mix of people who had experience of ILAT and those who didn't, to best prepare the manual and materials to prevent any important material from being omitted due to familiarity with the procedures. So, assistants and SLTs were approached that had experience of ILAT and those who did not. Unfortunately, it was very difficult to arrange a workshop to discuss the process due to the ill health of the people with aphasia who were willing to attend, and the busy schedules of the professionals involved. Therefore, each stakeholder was contacted separately either in person, via telephone or email for feedback and discussion of the development of the manual/handbook and Daily Intervention Log. The draft was given to all stakeholders to examine and provide feedback. Each stakeholder was asked to comment on the following: the clarity of the content, how difficult/easy it would be to complete a course of ILAT given the information in the manual/handbook, and if any further information was needed.

Table 13 Key Stakeholders

Stakeholder (N=??)	Experience of ILAT
Aphasia Survivor (n=2)	1 had not received ILAT but had completed SLT, 1 had experience with ILAT
Carers (n=2)	1 had observed ILAT and 1 who had not
Speech and Language Therapist Assistant (n=4)	1 had experience of working with people with aphasia and facilitating ILAT 3 had limited experience of aphasia
Stroke Association Communication Support Worker (n=1)	Trains and supports volunteers to facilitate groups
Speech and Language Therapists (n=3)	1 SLT who had no experience of ILAT and 2 SLTs who had experience of ILAT
Original developer of ILAT (n=1)	Developed and designed ILAT

3.10.1 Manual development

Prior to commencing this doctoral fellowship, the research SLT had delivered 4 groups of ILAT to people with aphasia as a service improvement project within the role of lead SLT for stroke in Northern Lincolnshire and Goole NHS foundation Trust. During this service improvement project one assistant acted as the second facilitator. Drawing on this personal experience of delivering ILAT, and supporting an assistant to facilitate ILAT combined with the information derived from the theoretical and narrative literature reviews, and observations in the originators clinic, A draft ILAT Manual for

the supervising SLT, Assistant-volunteer Handbook, and Daily Intervention Log for recording participant progress and supporting supervision by the supervising SLT was developed, which included the following content:

10. Introduction
11. Background and key principles of ILAT
12. Information about stroke and aphasia
13. Speech and Language Therapist Role
14. Assistant/Volunteer Role
15. Logistics of running the group (breaks, materials, daily schedule, room setup)
16. Description of the Language Action Games
17. Completing the Daily Intervention Log
18. References

3.10.2 Development of the Daily Intervention Log (DIL)

The Daily Intervention Log is an integral part of this research project as it is the feasibility of an SLT supervising ILAT delivered by assistants/volunteers that forms an essential component of what is being tested in the pilot trial and the potential inclusion of ILAT as a therapy on the NHS depends on whether it can be delivered efficiently. Therefore, a significant amount of time was spent focused on the feedback mechanisms that will allow an SLT to supervise and support assistants/volunteers and ensure participants are receiving the best intervention possible and that fidelity of ILAT is maintained. The DIL will also be used to assess the fidelity of ILAT delivery (see section 4.6.6 Fidelity assessment of ILAT for methods). The research SLT had extensive discussions and observations with the SLT delivering ILAT under the supervision of the originator which included the decision-making processes involved in progressing participants through the materials during the intervention and how to use clarification questions and prompting for participant management during ILAT delivery. This discussion allowed the research SLT to develop key information required to remotely supervise and progress participants through the therapy. Three draft versions of the daily intervention log were produced and consultation was sought from the key stakeholders. Unfortunately, consensus wasn't reached regarding the version of the form. Assistants felt they needed to use the DIL in practice to establish the best format. Therefore, all three versions were available for assistants/volunteers to select the form they wished to use during the first ILAT course delivered in this research project to determine which was most suitable (see Appendix 8).

3.10.3 Consultation results

Once the initial draft was completed consultation was undertaken to further develop the manual/handbook and Daily Intervention Log. The consultation included questions about the clarity

of the content and whether the manual provided sufficient description to allow delivery of ILAT using the manual.

3.10.3.1 Results from SLTs

Both the SLT who was delivering ILAT and the one who had no experience of ILAT felt strongly that it was essential to fully describe the methods used to help the participants to successfully take turns within the Language Action Games and more specifically what prompts, clues and questions to ask to make sure the games flow smoothly and prevent participants becoming unduly frustrated (138).Therefore, a detailed section was developed within the assistant/volunteer handbook as well as a record sheet, the Daily Intervention Log, that would educate and prompt assistants/volunteers to follow these essential components of ILAT delivery. The originator was also very concerned that assistants/volunteers did not destroy the behavioural relevance of the language embedding by looking at the participant's cards and giving more direct clues unless this became necessary where communication had completely failed. Following this advice, an additional section on playing the language action games was added to the assistant/volunteer handbook to attempt to convey this important component of ILAT.

The SLT who had little experience of ILAT commented that some further advice would be useful after assessing a patient, on how to then select the level of the cards and individual targets for each patient used to play the language action games and how to then integrate these separate targets for the four patients playing the game. Therefore, a case study was added to the SLT manual to demonstrate these processes. A criterion was also developed to determine how and when to progress patients on to a new set of targets or level of cards throughout the course of the ILAT following feedback from the assistant/volunteers provided on the Daily Intervention Log (see section 3.9.4 ILAT procedures). This criterion was piloted during the completion of ILAT courses in the pilot RCT.

3.10.3.2 Results from assistants

The assistant who had delivered ILAT and the one who had little experience of ILAT commented that it was not difficult to understand the manual and felt that with training and supervision it would be achievable to deliver ILAT following the assistant/volunteer handbook.

3.10.3.3 Results from person with aphasia and carer

The person with aphasia who had completed ILAT as part of the service improvement project felt it was essential that assistants/volunteers knew to give people with aphasia extra time to communicate the message, to 'listen to the end' without interrupting and then reflect what was

understood to confirm the success, or failure of the communicative exchange. As a result, the handbook was altered to emphasise allowing time for the person with aphasia to make full, independent attempts to communicate prior to giving any kind of prompting or support. The carer of a person with aphasia commented that the manual and clear and would allow the delivery of ILAT given training and supervision.

Therefore, the final manual and handbook for use in the first ILAT course in this research included the content listed in Section 3.10.1 Manual development with the addition of case studies for supervising SLTs, development of ILAT, and enhanced descriptions of how to play the language action games including scripts of communication exchanges and examples of clarification questions (Appendix 9).

3.10.3 Training for Assistants and Volunteers

A training seminar was developed following the consultation and preparation of the ILAT manual/handbook, and informed by the training delivered by Meinzer et al (2007) (122) for layperson delivery of ILAT (identified in the narrative review). The training was a two-hour session including an introduction to ILAT principles, procedures, materials, approaches to eliciting spoken language and how to feedback to the SLT. Practical elements of the training were scoring scripts of LAG turns on the DIL and playing the LAGs together. Each assistant/volunteer participated as a co-participant and co-facilitator before taking on the role as facilitators. Following training, assistants/volunteers completed a short questionnaire about the principles and practices of ILAT. In this way, the research SLT checked each facilitator's understanding of the procedures.

3.11 Conclusion

The overarching aim of this chapter was to describe ILAT, its underlying theory, mode of action, key elements and describe the faithful delivery of ILAT for this research. The theoretical review mapped the development of ILAT and its previous version CIAT/CILT resulting in a treatment diagram which identified five key components (components; targeting salience (language action embedding and behavioural relevance), targeting intensity and repetition (massed practice), targeting specificity (prompts and feedback),targeting use-it-and-improve-it (shaping and tailoring), and, targeting use-it-or-lose-it (constraint, barriers and learned non-use)), and the proposed underlying mechanism of action, Hebbian learning). The narrative review examined how ILAT has been reported in the literature finding that several studies did not report delivering all five key components and that these components were understood and implemented in inconsistent ways. Part 2 described the

development of a logic model, detailed intervention description, a treatment manual, training package and materials for the delivering the intervention (DIL). These outputs will be used to deliver and evaluate assistant/volunteer delivered ILAT in a pilot RCT compared to usual care in the NHS.

Chapter Four: Methods for the feasibility evaluation of ILAT: Pilot Trial and Qualitative Research.

In this chapter, the methods for the delivery of a feasibility study including a pilot trial of Intensive Language Action Therapy compared to usual care following the CONSORT Statement for pilot and feasibility trials (182) *and embedded qualitative research are described in detail.*

4.1 Study aims and objectives

The aims of this study were;

- To examine the feasibility of undertaking a randomised control trial to compare the clinical effectiveness of ILAT facilitated by trained assistants/laypersons (as in addition to usual care) with usual treatment in the NHS.

- To evaluate the feasibility and acceptability of ILAT delivered by trained assistants/volunteers

The objectives of this study were;

- To estimate recruitment rates.
- To assess the most appropriate and acceptable outcome measures to evaluate whether the goal of the ILAT intervention was achieved.
- To assess the feasibility of the randomisation process exploring any delays/difficulties in delivering group therapy in a timely way following randomisation.
- To assess the feasibility of delivering ILAT using therapy assistants/ volunteers.
- To explore the acceptability of ILAT delivered by trained therapy assistants/volunteers

4.2 Design

To address aim one a pragmatic, mixed method, parallel group randomised controlled pilot trial comparing Intensive Language Action Therapy (ILAT) facilitated by therapy assistants/volunteers (as in addition to usual care) with usual care was completed. A Randomised Control Trial (RCT) design was selected as the Cochrane review for Aphasia interventions has called for RCT's to strengthen the evidence for the treatment of aphasia (183). Further, ILAT has not yet been compared to usual care and this was the next step in the hierarchy of research evidence to determine the effectiveness of ILAT (184). The pilot trial aimed to test the methodology for evaluating the impact of ILAT for patients and service providers within the NHS to inform a future large, multicentre trial. An external

pilot was chosen rather than an internal pilot within a full RCT, as there was significant uncertainty in the trial and intervention procedures that need to be investigated before proceeding to a full RCT (185). The research examined the feasibility of using volunteers and therapy assistants to facilitate ILAT. The feasibility issues were: the process of recruitment; randomisation and group allocation stratified by severity; training therapy assistants and volunteers to deliver ILAT; and recording daily intervention data, feedback from therapy assistants/volunteers to supervising Speech and Language Therapist (SLT) and monitoring of treatment. It was crucial to pilot these procedures to test whether it is possible and practical to complete a definitive trial (182).

This trial was intended to pragmatically examine the effect of assistant/volunteer facilitated ILAT as a whole treatment package (as an addition to usual care) compared with usual care, another complex package of treatment under practical conditions. The pragmatic trial design allowed the research SLT to examine ILAT delivered in as close to possible the everyday clinical context in which it would be delivered within the NHS rather than controlling and dissecting the individual components of ILAT in a more explanatory approach (186). The Pragmatic Explanatory Continuum Indicator Summary (PRECIS) -2 tool was used to assess the degree of pragmatism with in the trial (187).

To address aim two an embedded qualitative study allowed the exploration of the perceptions, acceptability and experience of ILAT to the participants and service providers (assistants/volunteers). Semi-structured interviews were completed with participants and service providers (therapy assistants/volunteers) to explore acceptability of ILAT. Interviews also explored facilitators and barriers to success during ILAT. This data was compared with the quantitative data from outcome measure assessment using triangulation to more fully examine and explain the results.

The mixed method approach was in line with the 'feasibility' and 'pilot' stages of evaluation within the MRC framework for Developing and evaluating Complex Interventions to Improve Health (188). The terms pilot and feasibility are both used in the literature to describe work that is done in preparation for definitive evaluation in a RCT. There has been inconsistent use of these terms and a clear definition of each term has not yet been established. The National Institute of Health Research define feasibility studies as work done before a main trial to answer the question "can this be done?". The design then includes those aspects of the study that are considered uncertain so that they can be defined to improve the success of the definitive study. The NIHR also state that feasibility studies do not evaluate the outcome of interest. Whereas, the NIHR define pilot trials are a version of the main study that is run with a small number of participants to ensure the methods can be done and does include evaluation using the outcome measures (189). The Medical Research Council lists feasibility and piloting as testing procedures, estimating recruitment and retention and determining

the sample size but do not define the two as separate entities(190). Eldridge, et al. (2016) stated following a Delphi survey that feasibility and pilot studies were not mutually exclusive and instead that pilot studies are a subset of feasibility studies. Eldridge defined feasibility studies as those that were asking whether something can be done and if so, how. Pilot studies were defined as asking the same question but had a specific design in which a smaller version of part or all of a larger definitive study was completed (191).

For the purposes of this thesis the term feasibility study was used to describe the entire body of work which contained; the development of a treatment theory, and fidelity assessment combined with an iterative evaluation of the intervention to refine and define the intervention for the definitive trial, a pilot trial to test and examine trial procedures for a definitive trial, and a qualitative study to examine the feasibility and acceptability of the intervention to all stakeholders.

The qualitative study also aimed to take pragmatism as a world view, which allowed the research SLT to examine the data from different angles focusing on actions, situations and consequences that affect the success of ILAT (192). Pragmatism further allowed the research SLT to use all methods appropriate to assess, explore and address barriers to assistant/volunteer facilitated ILAT within the context of the NHS (193). Pragmatism as a worldview and pragmatic trial design allowed the research SLT to explore actions, situations and consequences that arose during assistant/volunteer facilitated ILAT within the clinical context of the NHS.

The internal validity of the pilot trial was assessed for: adequate concealment of treatment allocation schedule; adequate generation of allocation sequence; inclusion of all participants who were randomised in the analysis; and, adequate blinding as recommended by Schultz, and colleagues to reduce the risk of bias (194).

4.3 Study Setting

The study setting was a rural NHS Foundation Trust in England, United Kingdom which consisted of two general hospitals and one district hospital. Participants attended outpatient clinics in the two general hospitals which are referred to as Centre 1 and Centre 2. Participants also received usual care and outcome measurement in community clinics and in their own homes.

4.4 Eligibility

The following describes the eligibility criteria for participants with aphasia, carers, therapy assistants and volunteers.

4.4.1 Participant inclusion and exclusion criteria

Participants who had aphasia at least one-month post stroke were identified by therapists from within speech therapy databases or by the local Stroke Association Communication Support worker. The PhD candidate acted as the research SLT throughout this study. The research SLT then screened potential participants using the following criteria, which were devised in line with previous studies of ILAT (112,161):

Inclusion:

- Aged 18 or over
- Diagnosis of aphasia as a consequence of stroke (determined by research SLT)
- Onset of stroke at least 1 month prior to randomisation
- Able to repeat spoken words (determined by research SLT)

Exclusion:

1. Presence of cognitive or psychological conditions that would affect participation or consent such as memory problems, dementia or difficulties with attention based on medical diagnosis, patient/carer report and as judged by consenting research SLT during screening assessment.
2. Excessive fatigue (as they need to be able to tolerate the intensive nature of ILAT) as determined by the research SLT, the potential participant themselves and their carer if available.
3. Need for treatment in a language other than English (as ILAT was delivered in English).
4. Currently in receipt of intensive therapy at more than 2 hours of individual therapy per week.

Long term stroke survivors were included in this trial because studies have shown people with aphasia can improve with therapy after many months or years therefore it was appropriate to offer ILAT to those patients who have suffered with aphasia for many years and would like some further intervention. Currently there is little to offer patients who wish to re-access SLT services. Therefore there was no exclusion criteria based on maximum length of time post stroke.

4.4.2 Carer inclusion criteria

Carer participants were eligible to take part in the trial if they provided informal care to the trial participant including family members, spouses and friends, were over the age of 18 and had no significant memory or cognitive impairments.

4.4.3 Therapy assistant inclusion criteria

A previous agreement had been made within community and therapy team (which consisted of SLT, Physiotherapy, Occupational therapy, and Dietetics teams who all use assistants in usual practice) to release assistants from any allied health discipline already working within the trust to participate in

this trial. All assistants working within the trust were eligible to participate in the trial. All assistants needed to have up to date DBS, health checks, induction and mandatory training in-line with NHS employee requirements.

4.4.4 Volunteer inclusion and exclusion criteria

Eligibility criteria were checked at an interview with the research SLT.

Inclusion

1. Expressed interest in the role.
2. Competent communicator as determined at interview.
3. Dynamic, patient and encouraging as determined at interview.
4. Agreed to criminal records and health checks.
5. Able to participate for a minimum of 8 hours per treatment group.
6. Able to attend training.

Exclusion

1. Volunteers were excluded if they had any formal SLT training or experience with ILAT.

All volunteers were subject to compliance with NHS trust volunteering protocols including Disclosure and Barring Service (DBS) and health checks, identification and general induction including confidentiality and infection control. Rather than honorary contracts being organised, volunteers signed a code of conduct in accordance with the Department of Health's (195) volunteer guidelines and trust volunteering procedure.

4.5 Identification, screening and consent

The following described the individual procedures for the identification, screening and consent of participants, carers, therapy assistants and volunteers.

4.5.1 Identification of participants

Participants were recruited from Centre 1 and Centre 2 within the one NHS trust. Three methods of recruitment were used;

- Speech and Language Therapists (SLTs) were asked to identify potentially eligible past and present patients from their caseloads and database. The database included personal information such as full name, date of birth, contact details, GP, reason for admission to hospital/speech therapy service etc. This information was only seen by speech and language therapists employed by the NHS trust and was not accessed by any members of the wider research team. An accessible letter (see Appendix 10) summarising the trial was sent via post

(or given to the potential participant by their treating SLT if they were currently in receipt of face to face therapy).

- The research SLT attended the local Stroke Association Communication Support Group to explain the trial to group members and those who were interested in taking part were invited to provide their contact details. The Communication Support Coordinator was also asked to identify potentially eligible patients from their records. The accessible letter summarising the trial was sent via post and contact was made as described above.

- The NHS Trust participated in a recently completed SLT aphasia trial (Big CACTUS). A list of participants from the Big CACTUS trial that had consented to be contacted about further research were sent an accessible letter via post.

In all three cases an estimate of aphasia severity was provided to the research SLT. This allowed recruitment to be batched by severity and completed in phases (see
Figure 10 10). So, participants were targeted by severity in phases. This allowed treatment courses to be delivered stratified by severity of aphasia in mild-moderate and moderate-severe courses (see Chapter 3 section 3.9 Description of ILAT using TIDieR for details of ILAT course structure).

The letter sent in all three cases requested that the potential participant contacted the research SLT if interested. The research SLT also contacted the potential participants two weeks after receipt of the letter to check whether they were interested in participating.

4.5.2 Screening of participants

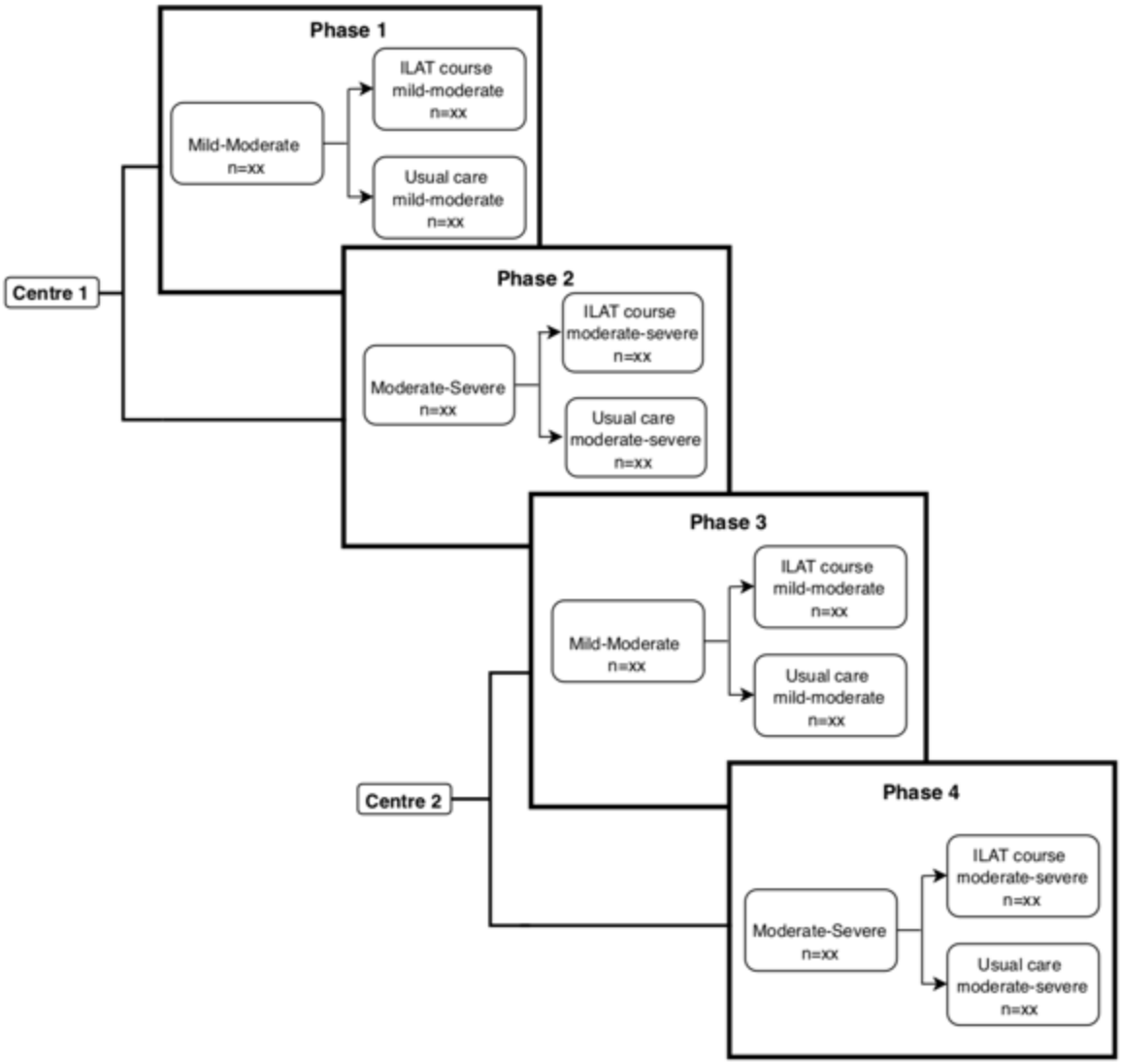
A screening log was completed by the research SLT indicating the method of recruitment. Screening data recorded and sent back to the Clinical Trials Research Unit data manager only included unidentifiable information including initials, gender and age.

After initial contact was established as described in Section 4.5.1, if interest was shown the research SLT arranged a visit to the potential participant at home. On the first visit the research SLT confirmed the time since stroke and, and that they were not currently receiving intensive SLT (more than 2 hours a week). The research SLT took verbal consent to complete a short naming test (10 minutes) from the Comprehensive Aphasia Test (196) to confirm the severity of aphasia. A score of 0-16 was considered severe, a score of 17-32 was considered moderate and a score of 33-48 was considered mild aphasia severity. Recruitment was batched to ensure that all participants recruited were able to be treated in the next available ILAT course (mild-moderate aphasia and moderate-severe aphasia). Batching meant that participants gave consent and completed baseline assessment and when there

were enough participants where baselines were completed that batch of participants was randomised.

Figure 10 10 shows the phases of recruitment. Initially, participants with mild-moderate aphasia were recruited from centre 1 and a treatment group delivered. Then, participants with moderate-severe aphasia were recruited from Centre 1 for the next group. This process was then repeated for Centre 2 resulting in four phases for recruitment (see section 5.3.1 Recruitment for actual recruitment).

Figure 10 Recruitment Phases



4.5.2 Consent of Participants

The research SLT then gained verbal consent to complete the short screening form Consent Support Tool (CST) (197) to determine the most appropriate style of trial information sheet to match the written comprehension ability of the potential participant. Four versions of the participant information sheets were developed that matched the levels identified by the CST. Level 1 included

plain English in paragraphs with key words emboldened for those with mild written comprehension difficulties (see Appendix 11). Level 2 used aphasia friendly short sentence and phrases with pictorial support for those with mild-moderate spoken and written comprehension difficulties (see Appendix 12). Level 3 supplemented level 2 by using PowerPoint with the use of animations to allow each idea to be presented individually with the addition of total communication support (i.e. gesture, writing, drawing etc.) before presenting the next idea for those with moderate-severe spoken and written comprehension difficulties. Level 4 was a short and simple pictorially supported PowerPoint that only conveys the basic elements of the trial for those with severe written and spoken comprehension difficulties (see Appendix 13). The correct level of information as identified by the CST was provided and discussed, then sufficient time was given for the participant to decide regarding participation. If willing to provide consent participants were asked to sign an accessible consent form (see Appendix 14). Those participants requiring Level 4 information were deemed unable to give consent, as not all the detail of the trial procedures was presented. Therefore, a consultee (relative or friend) was appointed and signed a declaration that they believed the participant wished to take part, after reading the full information sheet (see Appendix 15). After consent for participation was gained, participants were asked to give verbal consent at each stage before any trial procedure or treatment were delivered. A procedure for participants who lost the ability to consent during the trial was devised. A consultee was appointed to provide the above described declaration stating their belief that the participant still wished to continue in the trial. Any participant who lost capacity was to be withdrawn from the trial if a consultee could not be obtained. However, this procedure was not required during this trial.

4.5.3 Identification and Consent of Carers

Carers of trial participants were asked to participate and complete the baseline and four-month outcome measures during the home visits with the participant. Carers were provided with a carer information sheet (see Appendix 16) and provided written consent to participate (see Appendix 17).

4.5.4 Identification and consent of therapy assistants

The aim was to recruit six volunteers and four therapy assistants to facilitate ILAT. Assistants were approached and invited to participate by the research SLT starting with those in the speech and language therapy team and then extending to those in the physiotherapy, occupational therapy and dietetics teams. The research SLT made personal contact with assistants and described the research. Therapy assistants received an information sheet (see Appendix 18) and then signed a consent form if they were happy to participate (see Appendix 19).

4.5.5 Identification and consent of volunteers

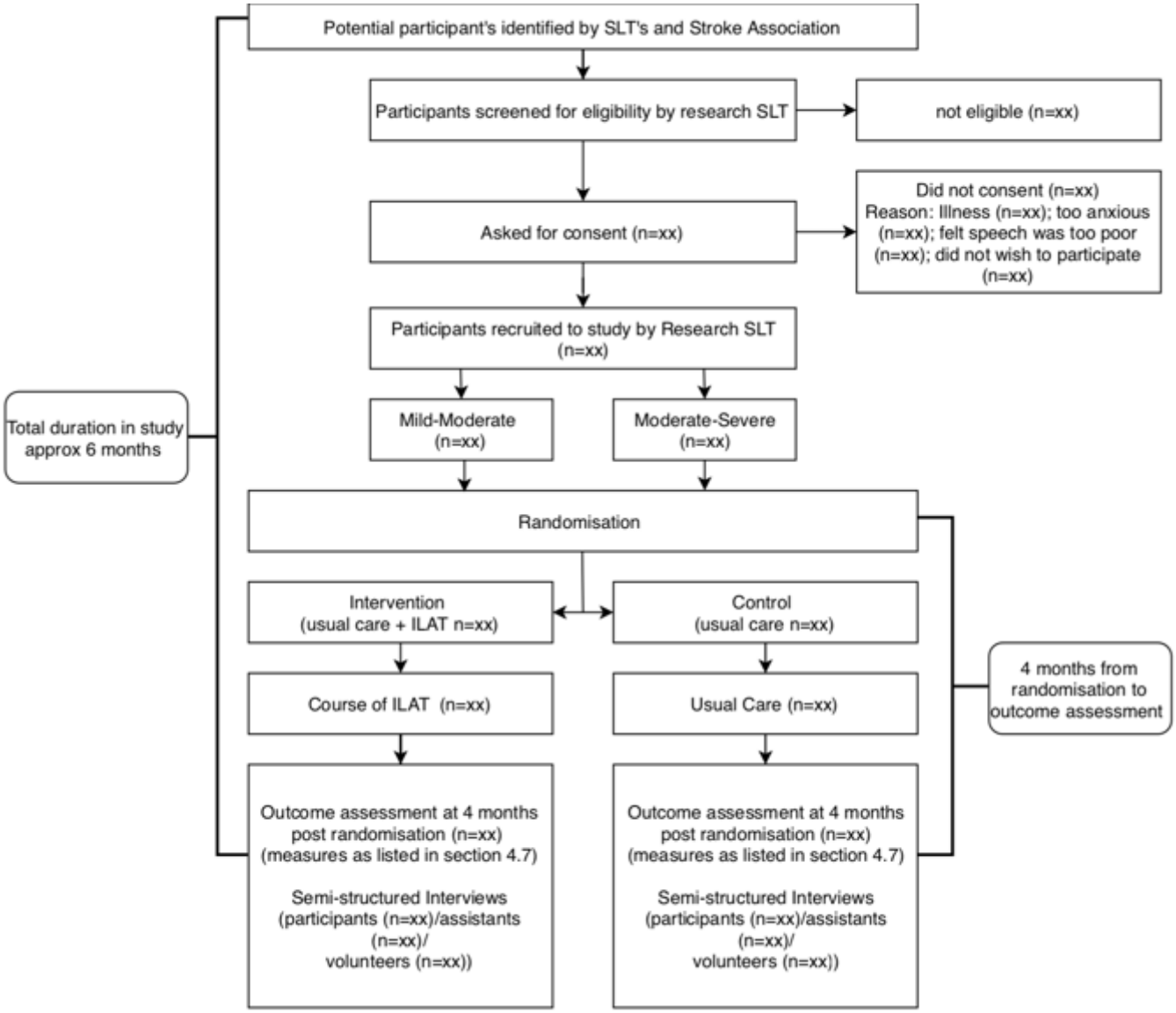
Volunteers were recruited using a recruitment strategy, which has been developed following the Department of Health's (195) volunteer guidance in conjunction with the volunteer coordinator at the host NHS trust. Existing volunteers throughout the trust were sent an invitation letter to determine if they were interested in participating in the study. Advertisements for volunteers were placed with Voluntary Action and the Stroke Association. Volunteers were provided with a person specification and role description, and were then required to write a short application detailing their skills and interest in the role. The volunteer then attended a short interview to ensure suitability for the voluntary role. Eligible volunteers were formally invited to take part in the trial, provided with an information sheet (see Appendix 18) and asked to provide written consent (see Appendix 19).

4.6 Randomisation

Patients were randomised at baseline in a 1:1 ratio to usual care plus Intensive Language Action Therapy (ILAT) or usual care. Randomisation was stratified by severity of aphasia (mild, moderate and severe) and centre and was conducted using a computer generated pseudo-random list with random permuted blocks of varying sizes, created and hosted by the Sheffield Clinical Trial Research Unit (CTRU). The research SLT enrolled participants into the randomisation system from which a list of intervention assignment was generated by the computer. No procedure for breaking the randomisation code was necessary as only the outcome assessors were blind to treatment allocation and there was no requirement for the outcome assessor to know the treatment allocation at any stage.

Figure 11 shows participant flow through the study. Outcome assessments were collected 4-months after randomisation was completed. It was anticipated participants would be actively participating in the study for approximately six months which allowed additional time to recruit and consent enough participants before randomisation to form a group for an ILAT course (see chapter 5 for details of actual time in trial and compliance with 4-month outcome assessment). ILAT courses lasted for 2 weeks and were contained within the 4-month between randomisation and outcome assessment. Usual care was recorded during the 4-month period between randomisation and outcome assessment.

Figure 11 Participant pathway through the study



4.6. Intervention

This study compared usual care to usual care plus a single course of ILAT delivered by therapy assistants/volunteers. Table 14 shows ILAT and usual care described using the TIDieR template for intervention description and replication (149).

Table 14 ILAT and usual care described using TIDieR

TIDieR item			
Brief name		**Intensive Language Action Therapy (ILAT)**	**Usual Care**
Why ?		There are 6 essential components that provide the theoretical underpinning and inform the practical delivery of ILAT; • Behavioural relevance – language action embedding • Intensive massed practice • Prompt and feedback • Shaping • Tailoring • Focusing/constraint (See section 3.5 for detailed discussion of each component, see section ?? for practical details of delivery in this research)	Is delivered according to the needs of the person with aphasia as determined by joint goal setting with SLT. Interventions may target; 1. improving communication through interventions that target language impairment, 2. improving functional communication through the use of compensatory strategies including communication aids, 3. provide social and emotional support through attendance at support groups or through individual support from the communication support worker from the stroke association 4. individual support from the stroke association, communication support from family members and carers
What?	**Materials**	Picture cards following Difrancesco, Pulvermuller and Mohr (57) (Appendix 9) Table top barriers Daily intervention log Appendix 8) Assistant/volunteer ILAT manual SLT supervision of ILAT manual Training package for assistants/volunteers	All materials were selected by the treating SLT to fulfil the goal of the intervention
	Procedures	Detailed procedures are provided in the intervention manual (**Error! Reference source not found.**)	Procedures were selected by the treating SLT to fulfil the goal of the intervention
Who provided?		Therapy Assistants-volunteers who completed training in the delivery of ILAT no longer than 2 weeks prior to delivering an ILAT course. Daily supervision and training was provided by a senior SLT (research SLT) who had experience with ILAT. 2 assistant-volunteer facilitators were allocated to each ILAT session.	SLT (band recorded), therapy assistant, volunteer, stroke association support worker
How?		ILAT was provided face- to-face in groups of 2-4	May be face-to-face, computer based, telephone calls; group or individual
Where?		Outpatient department in two NHS General Hospitals	Outpatient departments in the two NHS General Hospitals, participants own homes, community settings
When and How much?		30 hours provided 3 hours a day for 10 working days	All treatment dose provided according to the treating SLT clinical judgement
Tailoring?		Materials and focusing rules were tailored to participant interest and communication capabilities (see section?? For details)	All content of therapy sessions tailored to individual need by the treating SLT
Modifications?		The intervention was iteratively modified within a process evaluation based upon: field notes; attendance record;, fidelity assessment and semi-structured interviews with assistants/volunteers and participants; to maintain clinical data integrity and treatment fidelity	No modification of usual care was completed – all intervention provided in this arm was recorded for analysis.

4.6.1 Usual care arm

Usual speech and language therapeutic interventions were delivered to participants allocated to the usual care arm. These treatments differed per participant as determined by the treating SLT and included one to one, face-to-face therapy on a weekly basis with a Speech and Language Therapist or Assistant and/or a group session once a week. All content of therapy sessions was tailored to individual need by the treating SLT and included intervention targeting language impairment, compensatory strategies including the provision of communication aids, psychological support, attendance of stroke association communication support group or individual support from the stroke association communication support coordinator, or communication support from family members and carers. These treatments continued as deemed clinically appropriate by the treating SLT. Time in minutes of therapy and content were identified through the clinical records provided by the treating SLT and recorded by the research SLT.

Usual care was provided from the centres, other community NHS facilities, community support group settings or within the participant's own home. Long term stroke survivors were not accessing any SLT or stroke association support which resulted in 'usual care' being no contact from SLT or stroke association services for some participants (see chapter 5 for details).

4.6.2 Intervention arm (Intensive Language Action Therapy)

ILAT as described in 3.9 Description of ILAT using TIDieR was developed following a systematic review of ILAT, observations from the ILAT originators clinic, and in line with the methods outlined by Difrancessco and Pullvermuller's 2012 paper on the methods for the delivery of ILAT. ILAT was provided face-to-face in a group of between two and four participants with two facilitators either assistants or volunteers. See Chapter 3 for detailed discussion of ILAT. Four courses of ILAT were completed, two courses for the treatment of mild-moderate aphasia and two courses for the treatment of moderate-severe aphasia. Three courses consisted of ten sessions, and one course consisted of 9 sessions due to a bank holiday, held on Monday through Friday, on two consecutive weeks, for three hours a day for a total number of 30 hours. Each participant allocated to the intervention attended one course.

4.6.3 Intervention providers

Two facilitators either two therapy assistants or one assistant and one volunteer were allocated to each intervention session. One facilitator participated in the therapy providing a model for participants to follow. The second facilitator ensured the session ran smoothly throughout providing prompts to participants when communication breakdown occurs and completed a record of

communication exchanges on the DIL for the research SLT to provide supervision (see Appendix 8).

Volunteers received a local induction from the research SLT to ensure awareness of supervision structure, facilities, local area and emergency procedures. Training was provided by the research SLT once all volunteers/therapy assistants were recruited for each course and the date for course commencement was set, thus minimising any delay between training and commencing the first course of ILAT to ensure all training occurred no more than two weeks before facilitating a course. Training included familiarisation with the methods of ILAT through the training manual including a practical session playing the Language Action Game with the volunteers/assistants and practice completing the Daily intervention log (Daily Intervention Log) (see Appendix 8 and 9 for Daily Intervention Log, manual and training materials).

4.6.4 Materials

The cards used for the language action games were provided in packs. Each pack contained pairs of cards. There were six categories of cards; frequent words, minimal pairs, semantic categories, multi feature, spatial relationships, and actions (see section 3.9.3 ILAT materials). Card packs were also tailored to the individual interests of participants. The assistants/volunteers completed a Daily intervention log to record the progress of each participant (see Appendix 8 for detail).

4.6.5 Procedures

The procedure for the delivery of Intensive Language Action Therapy (ILAT) was described in a manual and handbook. (For details of the methods see Part 2: Development of ILAT delivered by assistants/volunteers and Appendix 9). The intervention was iteratively modified after each group was completed based upon barriers identified through: field notes; attendance record; fidelity assessment and semi-structured interviews with assistants/volunteers and participants; with the goal of maintaining clinical data integrity, treatment fidelity to support successful implementation of assistant-volunteer facilitated ILAT in a future large scale RCT. Interviews were taken after participation in each ILAT course for both assistants/volunteers and ILAT participants (see section 4.11 Qualitative study methods). This allowed solutions to issues identified to be remediated in an iterative process across each ILAT course. Fidelity checking (see section 4.6.6 Fidelity assessment of ILAT) and supervision sessions allowed the research SLT to check the effectiveness of implemented solutions after each ILAT course was delivered.

4.6.6 Fidelity assessment of ILAT

The fidelity of ILAT delivered in this study was assessed to determine the degree to which it was delivered as intended (198). The National Institute of Health Behaviour Change Consortium recommend that five domains of fidelity be considered when implementing behaviour change research. The five domains are study design, training, intervention delivery, intervention receipt and intervention enactment (199) . Chapter 3 outlines the study design and training domains. The methods used to examine fidelity to the domains of intervention delivery, receipt and enactment are described. Intervention delivery assessed whether therapy assistants/volunteers delivered only the intended intervention and no additional interventions, and maintained their competence and adhered to the treatment providing all components of ILAT. Intervention receipt assessed whether the participants understood, received and were able to complete the skills practised throughout the ILAT course and, intervention enactment assessed whether participants were able to perform the skills practised in the ILAT course in everyday life (199).

Therefore the specific aims of the fidelity assessment were to assess:

1) the adherence to the treatment manual and training and the faithfulness of the delivery of ILAT by therapy assistants/volunteers;
2) the completeness of the data collected on the Daily Intervention Log;
3) the accuracy of facilitators completing the Daily Intervention Log;
4) the amount of intervention delivered and received; and,
5) the participants and assistants/volunteers understanding and perceptions of ILAT including whether skills learned in ILAT impacted every day conversations.

Records of training delivery and attendance at training were used to assess the fidelity of training delivery and receipt. The fidelity of the content was not examined as all training was delivered by the research SLT and was iteratively refined during the course of the study. In the definitive trial the training would be delivered by SLTs at each site and the fidelity of delivery and receipt as well as content fidelity would need to examined. Adherence of ILAT delivery to the treatment manual was measured against the key components identified in the ILAT treatment diagram (see Figure 7 pg. 62). Table 15 details the fidelity assessment components, the theoretical basis (hashed numbers refer to Figure7) and a short description of each component. Observations of video recorded ILAT sessions were completed by the research SLT who had developed the training manual and the ILAT treatment diagram. Each component was given a score of two if it was delivered, one if there was some deviation or substandard delivery or a score of zero if it was not delivered at all. Thus, the maximum score for an ILAT course was 18 and the minimum zero.

Table 15 ILAT components assessed for delivery

Components	Theoretical basis	Component description
Group	Salience	Delivered in group of 2-4
Card exchange	Salience	Cards physically exchanged at the end of each LAG turn or language action embedding; facilitated by the process of accepting or denying a proposed activity
LAG	Salience	Language Action Games completed with requesting/planning tasks
Intensive and massed delivery	Intensity matters Repetition matters	ILAT delivered for 3 hours a day for 10 working days
Prompting	Specificity	Clarification questions used in line with manual Avoiding clues, first sound and repetition prompts
LAG complexity and component rules	Use-it-and-improve-it Use-it-or-lose-it	All rules used and modelled/explained as appropriate Providing reinforcement contingencies to feedback about performance on LAG rules
Stimulus materials	Use-it-and-improve-it Use-it-or-lose-it	Stimulus cards used that matched the communication competence of participants Stimulus cards used that matched the interests of the participants
Barriers	Use-it-and-improve-it Use-it-or-lose-it	Barriers placed between participants to force the use of spoken communication
Participants working at the upper limit of communicative competence	Use-it-and-improve-it Use-it-or-lose-it	Ensuring participants are given time and appropriate prompts and feedback to encourage best effort from participants

Completeness of the Daily Intervention Log was assessed through the analysis of missing data. The components of the Daily Intervention Log analysed for missing data were card set, type of LAG, duration of LAG, rule complexity, appropriateness and prompts. Unfortunately, there was no way of assessing whether rule components were missing data or simply not used by participants so this component was omitted from the fidelity assessment.

Accuracy of Daily Intervention Log completion was assessed through the review of video recorded sessions of ILAT courses by the research SLT. The accuracy of the Daily Intervention Log completion was essential as the research SLT made decisions about card sets and individualised rules for participants based on the Daily Intervention Log and discussion with the therapy assistants/volunteers. The Daily Intervention Log completion and discussion were an integral process in determining whether an SLT could remotely supervise and progress participants though an ILAT course. The research SLT scored each turn of each LAG in a sample of between two and five sessions of an ILAT course on the Daily Intervention Log and compared whether the records of the facilitator completed Daily Intervention Log matched the research SLT observation Daily Intervention Log. The sampled videos were randomly selected from across each ILAT course. The components assessed were rule complexity, rule components, appropriateness, number of clarification questions and prompts required as these are the components that record participant progress.

4.6.6.1 Assessment of intervention delivery, receipt and enactment

To assess the amount of intervention delivered the number of minutes of ILAT was measured per Language Action Game through the use of a timer which was recorded by the therapy assistants/volunteers on the Daily Intervention Log (see Appendix 8). The research SLT maintained a log of the time required for supervision and the issues discussed to inform a future larger study. To assess the amount of intervention that was actually received an attendance record was completed by the therapy assistants/volunteers on the Daily Intervention Log. Progression through increasingly more complex cards sets, improvement in appropriateness rating and a reduction in clarification questions were used as measures of intervention receipt, assessing whether participants were understanding ILAT and able to complete ILAT tasks. Enactment was assessed through the clinical outcome results and qualitative interview data.

4.7 Outcomes

4.7.1 Outcomes to assess study aim one: feasibility of RCT

Table 16

Table 16 summarises the outcomes to achieve study aim one: to examine the feasibility of undertaking a randomised control trial to compare the clinical effectiveness of ILAT facilitated by trained assistants/volunteers with usual care which were:

1. feasibility of recruitment and retention of participants – number of participants recruited per month and in a 16-month period, number of participants identified in order to recruit the desired number of participants (consent rate), completion rates of primary outcome (attrition) and field notes to record and examine contextual factors;
2. acceptability of the research procedures – as described by participants through interviews and contextual factors recorded through the collection of field notes; and,
3. feasibility of randomisation and allocation to treatment arm (ILAT) through the description of how groups were formed (field note data), the time taken to form groups and the number of four-month outcome measures completed within one month of the 4-month post randomisation time point, and the percentage of people eligible who consented to be randomised.

Table 16 Outcomes to assess aim one

Outcome	Measure
Feasibility of recruitment	Participants recruited per month Consent rate Field notes
Feasibility of retention	Completion rates of clinical outcomes
Acceptability of research procedures	Participant interviews, field notes
Feasibility of randomisation and allocation to treatment arm	Field notes on randomisation and course formation Time in days from randomisation to intervention receipt Time in days for baseline to intervention receipt Time in days from baseline to 4clinical outcomes Number of clinical outcomes collected per protocol
Acceptability of clinical outcome assessment	Completion rates of clinical outcomes Participant Interview data Field notes

4.7.2 Outcomes to assess study aim two

Table 17 summarises the outcomes that were used to assess aim two: To examine the feasibility of delivering ILAT using assistants/volunteers the following outcomes were selected;

a. Acceptability of ILAT to participants, assistants/volunteers – as described through qualitative interviews and field notes,
b. Feasibility of delivering ILAT by assistants/volunteers under the supervision of an experienced SLT through piloting the training and manualized procedures for the delivery of ILAT, examining the burden of supervision for the research SLT including the total number of minutes required per ILAT course and field notes that provided context,
c. Treatment fidelity of ILAT – through the observation/video recording, analysis of a sample of treatment sessions, records of attendance and minutes delivered and field notes that provided context (see section 4.6.6 Fidelity assessment of ILAT),
d. Facilitators and barriers to ILAT success – as described by participants through qualitative interviews and field notes recorded by the research SLT that provided context.

Table 17 Outcomes to assess aim two

Outcome	Measure
Acceptability of ILAT	Qualitative interviews with participants and assistants/volunteers
Feasibility of ILAT delivered by assistant /volunteers	Piloting training Piloting manualised procedures The number of minutes of supervision Recruitment and retention of assistants/volunteers
Treatment fidelity	Adherence to manual Completeness of Daily Intervention Log Accuracy of Daily Intervention Log Number of minutes of therapy delivered Participant attendance records
Facilitators and barriers to success	Participant, assistant/volunteer interviews

4.7.3 Clinical Outcomes

Since the completion of this study a core outcome set was published in 2019 (200) but was not available at the time of commencing this study. Therefore, outcomes were selected through reference to existing trial protocols that examined similar populations (Big CACTUS (201)) and assessed the aim of ILAT which was to improve conversation. Table 18 gives a summary of the clinical measures used in this study. The primary clinical outcome was conversational ability rated by a trained SLT blinded to treatment arm. This measure was chosen as the longer-term outcome of ILAT was to improve the conversational ability of people with aphasia (see Figure 7 (57)). Video recorded conversations, that were approximately ten minutes in length, were made at baseline by the research SLT and at 4-month outcome assessment by assessors blind to treatment arm. The research SLT compiled a list of between six and ten questions that related to topics of interest for participants. The research SLT then video recorded a conversation using the pre-selected questions and total communication methods to support the conversation. The assessor used the same pre-determined questions to record a conversation at the 4-month outcome. Therapy Outcome Measures (TOM) (202) Activity scale, following the procedure described by Hesketh, et al (2008) (203) and Impairment scale were used to rate the conversational ability at each time point (see Appendix 21 for scale and instructions) The TOMs were selected as this measure had previously been used to assess conversation in research and it was not labour intensive to administer or score. The ratings were made after the 4-month outcomes were collected. Once both the baseline and 4-month outcome conversations were recorded an SLT who was blinded to treatment allocation and time point (baseline/4- month outcome) was given the baseline and 4-month outcome video recordings in

pairs to rate. The TOMs activity rating scale has been reported to have excellent intra-rater and good inter-rater reliability (203). The impairment scale has not been used in this way in research to date but follows the same procedures as the activity rating and on this basis was trialled for this research and has excellent intra-rater and good inter-rater reliability (202).

The following secondary clinical outcomes have also been selected to further examine the clinical impact of ILAT to measure language improvements that are intermediate outcomes which are expected to lead to the longer-term outcome of improved conversation (naming words and pictures and grammatically complete and complex sentences (see Figure 7 ILAT treatment diagram and Figure 9 ILAT logic model pg. 88);

a. Naming ability was measured using the Comprehensive Aphasia Test (CAT) subtest Naming Objects (196) as ILAT aims to improve the ability to name words and pictures.

The CAT naming objects required the participant to name objects through the presentation of a series of pictures. Participants received a score of two if the picture was correctly named within 5 seconds, a score of one if the participant named the object incorrectly but corrected the response without any prompting from the assessor, and a score of zero was given for an incorrect answer including if a sound error was produced for example ("dable" for "table").

- Discourse ability sentence production was measured using the CAT Picture Description as ILAT aims to improve the ability to produce more grammatically complete and complex sentences (204). This subtests of the CAT assessed the content, complexity and completeness of sentences produced.

The CAT picture description required the participant to describe a picture. The number of correctly used information carrying words was counted, the number of inappropriate information carrying words for example semantic ("table" for "chair") phonemic ("dable" for "table") or jargon words was subtracted from the number of correct words. Then a rating was made for syntactic variety for example if varied noun, verb, adjectival and prepositional phrases or embedded clauses are used. A rating was also made assessing how well grammatical representations are formed for example using the correct inflection of auxiliaries, appropriate tense, number counts and required participles. These two ratings are completed on a 6-point scale that allows mid-point ratings. A further rating for speed was completed ranging for significant, consistent delay to normal speed of delivery on a 3-point scale with midpoints allowed.

The CAT including the object naming and picture description subtests, was reported to have good

inter-rater reliability and test-retest reliability and good face and concurrent validity making it an appropriate and robust outcome to use in research (205).

b. Participant rated perceptions of communication ability was measured using the Communication Outcome After Stroke (COAST) (patient rated outcome measure) (206) as ILAT was reported to improve confidence and participation in everyday activities and these domains are measured within COAST.

The COAST is a Patient Rated Outcome Measure (PROM) that examines the participants own opinions and feelings about their communication competence across different settings (familiar/unfamiliar people, individual/group), communication domains (receptive, expressive, reading, writing), change since aphasia onset and overall quality of life. Participants are asked questions and give a rating from a 5-point scale ranging from completely unable to as good as before my stroke. The COAST was reported to have good test-retest reliability, construct validity and good acceptability making it appropriate to use for this research.

c. Carers perceptions of participant communication ability was measured using the Carer COAST (carer rating of participant communication) (206) to further examine the potential impact of ILAT on confidence and everyday activities from the carer perspective.

The carer COAST is a self-administered PROM that examined the carers own perceptions on the participants communication across the same set of questions as the COAST. The carer COAST was reported to have good test-retest reliability, construct validity and good acceptability making it appropriate to use for this research.

d. Health related quality of life was measured using the EQ-5D-5L aphasia friendly version (207) and proxy rated EQ-5D-5L (208). The aphasia friendly version of the EQ-5D-5L has not yet been validated however collecting the self-reported quality of life of people with aphasia was essential to determining the success of ILAT. Therefore, the EQ-5D-5L proxy was also completed.

The EQ-5D-5L was used to evaluate the participants state of health across five domains: mobility, self-care, usual activity, pain/discomfort and anxiety/depression. Participants rate the five domains using a five-point scale. An aphasia friendly version incorporated images to support the communication of people with aphasia. The EQ-5D-5L was included in this trial to pilot the burden of completing the full package of measures required for health economic evaluation in a future trial. No plans were made to attempt health economic evaluation in this study;

e. Carer health related quality of life was measured using the CarerQoL (209)

The CarerQoL assess the subjective burden of care responsibilities for informal carers through a self-administered PROM. The CarerQoL was completed to allow health economic evaluation in a larger definitive trial and like the EQ-5D-5L was completed to assess the burden of outcome measures.

Table 18 Summary of clinical measures

Outcome	Measure	Scoring	Method of Collection	Time point
Change in conversational ability	10-minute video recorded conversation structured around topic of personal interest rated using the TOMS activity and impairment scales	TOMS is an observational rating from 0 (unable to communicate) to 5 (communicates effectively) half points allowed resulting in an 11 point scale the CMD is 0.5 of a point and a higher score indicates better language function	Video recordings taken by SLTs blinded to treatment arm. Videos randomised and rated by separate SLT blinded to allocation and time-point	• Baseline • 4-month post randomisation
Change in naming ability	Naming subtest of the Comprehensive Aphasia Test	CAT Naming is a score out of 38 the CMD is a 4 point increase in performance and a higher score indicates better language function	Taken by SLTs blinded to treatment arm	• Baseline • 4-month post randomisation
Change in discourse	Picture description subtest of the Comprehensive Aphasia Test	CAT Picture description has no ceiling score and can be a negative score, the CMD is a 10% increase in performance and a higher score represents better language function	Taken by SLTs blinded to treatment arm	• Baseline • 4-month post randomisation
Change in patient perception of communication and quality of life	COAST self-reported questionnaire and EQ-5D-5L aphasia friendly version/proxy	COAST is a 20 item scale a higher score indicates perceived better language function	Self-report facilitated by SLTs blinded to treatment arm Report of participants quality of life from a relative or carer	• Baseline • 4-month post randomisation
Carer quality of life	Carer COAST and Carer-QOL	Carer COAST is a 20 item scale a higher score indicates better perceived communication function Carer-QOL	Self-administered	• Baseline • 4-month post randomisation
Cost of intervention	Diaries of time spent supervising and delivering intervention	NA	Minutes of supervision recorded in research SLT field notes Minutes of ILAT delivered recorded on Daily Intervention Log by assistants/volunteers	During ILAT course 1 -4
Cost of usual care	Diaries of time spent supervising and delivering usual care	NA	Data collected from usual treating therapists clinical records and participants	A 4-month time period from randomisation to outcome assessment
Carer perception of change in communication	Carer COAST	Carer COAST is a 20 item scale a higher score indicates better perceived communication function	Self-administered at baseline and 4 months	• Baseline • 4-month post randomisation

4.7.3 Criteria for proceeding to future definitive trial

The feasibility and acceptability outcomes formed the criteria for proceeding to a definitive trial. The criteria were:

- a minimum recruitment rate of one participant per month in line with other RCTs in stroke and health research (210);

- completion rates for the primary outcome of at least 80% in line with other health research trials (211);
- adherence to treatment protocol as measured by intervention attendance and fidelity assessment;
- positive reports from stakeholders about the feasibility and acceptability of all trial and ILAT procedures; and,
- recruitment and retention of assistants and volunteers.

4.7.4 Data collection and management procedures

Baseline assessments were collected by the research SLT prior to randomisation to ensure measures were taken blind to treatment allocation and 4-month outcomes were completed by four trained assessors who were SLTs within the SLT department of the NHS trust. All assessors had completed the Good Clinical Practice training provided by the National Institute of Health Research. All assessors underwent training to ensure assessments and Case Report Forms were completed correctly. An inter-rater-reliability exercise was completed to ensure the assessments were completed consistently between assessors. The benchmarking exercise consisted of watching two video recordings of people with aphasia being assessed with the subtests of the CAT naming objects and picture description and scoring the tests. Scores were compared between assessors. Any differences were discussed and a consensus agreed on how to interpret scoring instructions consistently. If a larger than four point variation occurred the research SLT met with the assessors to discuss the differences and formed a consensus on scoring that was shared with all assessors as appropriate. For the TOMs ratings impairment and activity detailed written instructions and training were provided by the research SLT to the assessor. As only one assessor completed all ratings, inter-rater reliability was not assessed.

4.7.4.1 Case Report Forms

The University of Sheffield provided data management support through the Sheffield CTRU. With the support of a data management team the research SLT selected the Case Report Forms (CRF) that were used for outcome assessment. Several of the CRFs had previously been created for other trials supported by the CTRU and were used for this study. However, the CRF for the Daily Intervention Log was unique to this study. The details of its development with the collaboration of the data manager, therapy assistants and research SLT are reported in section 3.10.2 Development of the Daily Intervention Log (DIL).

4.7.4.2 Database Management

The CTRU provided access to a database for the recording and collation of all CRF data. A database

specification was drawn up based on the case report forms and Sheffield CTRU standard operating procedures were used as the basis for the database development. The database was held on CTRU's secure in-house data management system, with access controlled by usernames and encrypted passwords. A comprehensive privilege management feature was used to ensure that users had a level of access appropriate to their needs. The database underwent thorough user testing before it was deployed and users granted access. The research SLT attended regular meetings including Trial Management Group (TMG) meetings to ensure data quality and completeness. Data validation rules were defined by the data management team and research SLT and validation reports were run regularly to generate queries for resolution by the research SLT. The data management team supported the research SLT to conduct quality control checks on all input data. A data manager or the research SLT checked all data in the database with the CRF's and any missing data was collected as appropriate or marked as permanently missing. Any discrepancies were clarified with the research SLT and data was resolved as appropriate. The research SLT checked all queries generated by the data validation rules to ensure the data was an accurate representation of the CRFs and all data was collected per protocol. All queries were completed before the lock and cleaning of the data for statistical analysis. For full details of the Data Management Plan please see Appendix 22.

4.7.5 Blinding

Participants were randomised after consent and baseline assessment to ensure the research SLT was blind to treatment allocation at baseline assessment. It was impossible to blind any of the participants, therapy assistants/volunteers or the research SLT to the intervention provided. However, trained assessors who were SLTs completed the 4-month outcome measures blind to group allocation and were not involved in recruitment or intervention. If blinding was broken through patient conversation, assessors recorded this on an unblinding form. The conversational ratings using TOMs were completed by a separate trained SLT who was blind to treatment allocation and timepoint (baseline/4-month outcome).

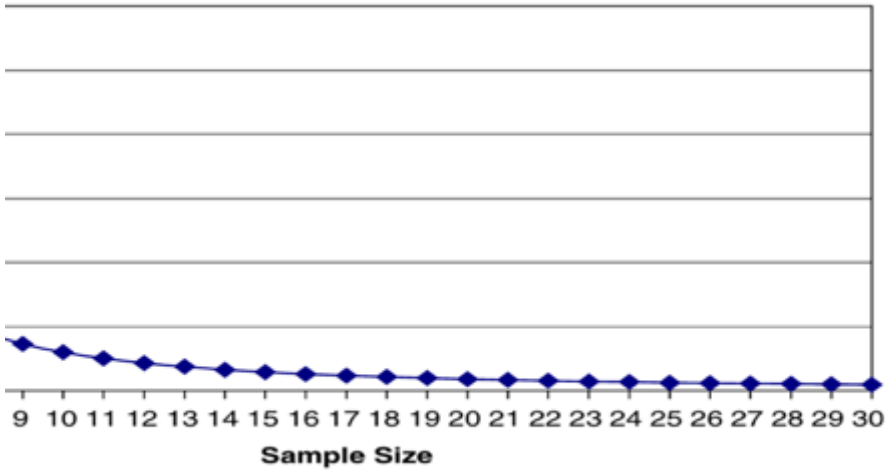
4.7.6 Changes to trial outcomes after commencement of trial

No changes to the trial outcomes were made after the commencement of the trial.

4.8 Sample Size

The study aimed to include 12 evaluable participants per arm. This sample size was not based on any formal power considerations but was considered sufficient to estimate the parameters for the design of a future trial based on advice from Julious et al. (2016) in a paper exploring minimum numbers of participants required for sufficient information in pilot trials (212), (see Figure 12).

Figure 12 Gain in precision for each increase of 1 in the sample size per arm for a parallel group trial pg. 288 (212)



The trial aimed to recruit 32 participants in total so that four treatment groups (of 4 participants) could be formed and to allow for potential dropout within the period of 16 months (groups can continue to run with 3 participants) down to 24 evaluable participants. It was not intended that effect size for the full trial would be calculated from the pilot trial as the sample size was too small to provide reliable estimates. Instead we planned to base future sample size calculations on published data from trials using similar populations and similar clinical outcome measures (e.g. Big CACTUS (201) CALM (213)).

Whilst this pilot trial was not aiming to estimate the sample size for a definitive trial, the intra-cluster correlation coefficient (ICC) was calculated as ILAT was delivered in clusters of four whilst analysis of the outcomes was at the level of the individual. The clustering of participants in this case by severity of aphasia and for ILAT delivery causes a degree of "relatedness" between the participants that means the responses to ILAT may be similar across participants treated in the same group. Calculating the ICC allowed an inflation factor to be calculated (214).

4.9 Statistical analysis

A Statistical Analysis Plan was developed with the support of a senior statistician from the Sheffield CTRU (see Appendix 23). As a pilot trial, the primary outcomes focused on the feasibility of delivering the main trial and as such the main analysis was descriptive. The data from this feasibility study was used to estimate the consent rate, attrition rate, and the variability of the clinical outcomes in the trial population.

4.9.1 Eligibility and Consent Rate

The following figures were reported either in the CONSORT flow diagram (see Figure 15 or in Table 25):

The number of potential patients who:

- were potentially eligible as identified by the study team at each participating centre;
- were approached for the study;
- were recruited per month;
- completed each assessment at baseline and 4-months;
- were randomised to treatment or control;
- were withdrawn and lost to follow up by treatment group and overall;
- discontinued ILAT and the reasons for discontinuation;
- were included and excluded from analysis and the reasons for exclusion by treatment group and overall;
- had missing outcome measures at baseline and/or 4 months by treatment group and overall;
- deviated from protocol by treatment group and overall.

The number and percentage of patients refusing consent overall and by reason category were reported as a proportion of all patients that refused consent.

4.9.2 Feasibility of randomisation and ILAT course formation

To assess the feasibility of randomisation and ILAT course formation the number of days from baseline assessment to randomisation, consent to treatment, randomisation to 4-month outcome assessment and from baseline to 4-month outcome were calculated per treatment arm, centre and individual ILAT course. Total duration of trial participation in months was calculated using consent to 4-month outcome assessment dates.

4.9.3 Attrition Rate

The rate of attrition was reported (defined as the proportion of the consented and randomised participants who withdrew or were lost to follow up). The reasons for attrition, where provided, were reported as number and percentage in category. Attrition was presented by treatment arm and centre.

4.9.4 Baseline characteristics

The baseline demographics and clinical characteristics of the patients were reported. Stroke characteristics were reported. Stroke History which includes the date of the patient's most recent

stroke was recorded. For the categorical variables, (e.g. centre), the number and percentage of patients in each of the categories and the total number of observations were presented. For the continuous variables (e.g. age) mean and SD were presented or median and inter quartile range (IQR) depending on the distribution of the data. The number of observations used in each calculation was presented alongside the summaries. Stroke characteristics were reported. Stroke History which includes the date of the patient's most recent stroke were recorded. For the categorical variables, (e.g. centre), the number and percentage of patients in each of the categories and the total number of observations were presented. No statistical significance testing was done to test baseline imbalances between the intervention arms but any noteworthy differences were descriptively reported.

4.9.5 Interventions

Time in minutes of both ILAT and usual care were collected and reported in Table 42. For the usual care arm type of intervention and Banding of SLT or assistant who delivered the intervention were reported in section 5.5 Usual Care.

4.9.6 Clinical outcomes

Descriptive statistics were calculated for the clinical outcomes (COAST, Carerqol-7D, Carer COAST, EQ-5D-5L Aphasia Friendly, EQ-5D-5L Proxy, TOMs Activity and Participation, CAT Naming, CAT picture description) using the SPSS version 26 software. The mean and SD were presented or median and inter quartile range (IQR) depending on the distribution of the data. The number of observations used in each calculation were presented alongside the summaries. No statistical significance testing was done to test baseline imbalances between the intervention arms but any noteworthy differences were descriptively reported. All baseline summaries were presented and reported for each treatment group and in total.

The analysis was performed on an ITT basis and the final analysis was performed after data lock by the research SLT under the supervision of the Trial Statistician. The mean difference for the primary and secondary 4-month clinical outcomes were calculated with baseline outcome as a covariate to allow adjustment for baseline. The effect size was the difference in mean scores between the ILAT group and the usual care group following adjustment for baseline along with the associated 95% confidence intervals. The standard deviation was also calculated. This difference and its associated confidence interval were used to check that the likely effect was within a clinically relevant range. The clinically relevant mean difference for the primary clinical outcome, TOMs impairment and activity scales was 0.5.

For the primary clinical outcome (TOM's) Activity and Impairment scales at 4-months, the intra-cluster correlation (ICC) for patients treated in each ILAT course was estimated. The sample size was calculated using published studies of similar trials in similar populations (CACTUS, CALM). However, ILAT was delivered in groups which increases the risk of ICC. Therefore the ICC calculation was used to determine the increased number of participants required in the ILAT arm to account for ICC. The median completeness rates for the PROMs (COAST, Carer COAST, Aphasia friendly EQ5D, proxy EQ5D and CarerQoL) were calculated per treatment arm and are presented in Table 35.

4.10 Adverse events

Adverse events were recorded and reported in line with CONSORT(182). Adverse events associated with the intervention were not anticipated given the low risk intervention (in line with similar studies managed by CTRU). Adverse events were recorded by therapists on the CRF and database. Hospital admission, or any other event considered serious were reported as Serious Adverse Events (SAEs). Further stroke related events were not reported as SAEs because these are expected within this population. The SAE was assessed for severity and relationship to ILAT and reported in accordance to CTRU Standard Operating Procedure PM004.

4.11 Qualitative study methods

The qualitative study was designed to address aspects of both aim one and aim two, the feasibility and acceptability of ILAT delivered by trained therapy assistants/volunteers in an RCT in the NHS. Semi-structured interviews were completed. Questions were designed to explore any facilitators or barriers that would support or hinder ILAT delivered by therapy assistants/volunteers and also to identify factors that could be address to best support the success of ILAT. Further qualitative data was ascertained through the field notes and observations of the research SLT which allowed the documentation of important contextual factors that may have impacted the delivery and success of ILAT(215). These notes included information about the day to day logistics of recruitment, training, set up, and supervision of delivery of assistant/volunteer led ILAT.

4.11.1 Sampling strategy

All participants and assistants/volunteers who were recruited to the pilot trial were eligible and invited to complete a semi-structured interview (see section 4.4 Eligibility). Consent for completion of the interviews was taken at the time of consent to participate in the pilot trial.

4.11.2 Qualitative interviews

Semi-structured interviews were conducted with participants and therapy assistants/volunteers. Participants in the ILAT arm were interviewed once after completion of the ILAT course. Repeated interviews were collected from assistants/volunteers after delivery of each completed course of ILAT. Therefore, it was possible for a single assistant/volunteer to complete up to four interviews. Each round of interviews was completed prior to the start of the next course of ILAT to allow the participant and assistant/volunteer responses to influence the training of assistants/volunteers and the delivery of the next ILAT course. Data saturation, the point at which no new information is identified through data analysis, is usually used to determine, when data collection can cease. However, in this study there was a finite number of participants and assistants/volunteers. Therefore it was not possible to continue to collect data until saturation occurred instead data collection continued until all willing participants and assistants/volunteers were interviewed and coverage of the themes was assessed. Additionally, a sample of usual care participants were interviewed after all individual trial procedures were completed to assess the acceptability of the trial procedures. Interviews for the usual care arm were collected until data saturation occurred meaning that no new information emerged from the data (216). Data saturation occurred after three interviews.

Qualitative researchers aim to collect high-quality data using informants who are articulate and can clearly reflect on and describe their experiences (217). However, the impact of aphasia affected the informant's ability to clearly articulate and describe experiences and thus the quality of the data collected (218). Nevertheless, it was essential that the experiences and opinions of people with aphasia, about the treatment and research of aphasia, were collected and reflected in the ongoing pursuit of evidence-based interventions for this challenging population. Therefore, the onus was on the research SLT to facilitate the collection of high-quality data (218), and a procedure was developed informed by the methods described by Luck and Rose (219) and piloted to collect this important data (see section 4.11.4 Procedures for semi-structured interviews).

4.11.3 Topic Guides

The topic guide development drew on the research SLTs knowledge of ILAT, the logic model of ILAT (see Figure 9) and three key models / frameworks:

- the Capability, Opportunity and Motivation (COM-B) model of behaviour change (220). COM-B is a psychological model that attempts to incorporate all mechanisms of human behaviour change in the development and implementation of behaviour change interventions;
- the Theoretical Domains Framework (TDF) (221) which explores implementation problems for health care providers and participants in order to inform intervention development; and,
- the Theoretical Framework for Acceptability (TFA) which examines the degree to which

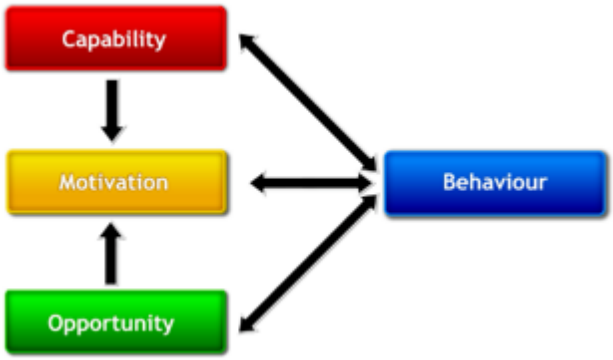
participants receiving an intervention and health care providers delivering an intervention perceived it to be appropriate based on anticipated and experienced cognitive and emotional responses to the intervention (222).

4.11.3.1 The Capability, Opportunity and Motivation model of behaviour change

The COM-B model of behaviour change (220) explores how capability, opportunity and motivation interact to produce behaviour (see

Figure 13 13). Capability was defined as the individual's psychological and physical capacity to engage in the activity concerned in this case communication in everyday life and in the intervention/ILAT. Capability in this model is divided in to the physical capability (CP) and the psychological capability (CPs) and includes the required knowledge and skills to engage in the behaviour of interest. Opportunity examines all the factors that lie outside the individual that make communication in everyday life possible or prompt it and are divided into physical opportunity (OP) and social opportunity (OS). Finally, motivation was defined as the brain processes that energize and direct behaviour and was divided into reflective (MR), social (MS) and automatic motivation (MA). These three components then interact and form the behaviour that then influences the individual components again (220). This framework allowed the research SLT to examine barriers or facilitators to the success of ILAT and gain insight into the what factors may need addressing to ensure future success of delivering ILAT facilitated by assistant/volunteers in a full scale trial.

Figure 13 COM-B a framework for understanding behaviour from Michie et al. 2011 pg. 4 (220) **.**



4.11.3.2 The Theoretical Domains Framework (TDF)

The Theoretical Domains Framework (TDF) was created to simplify and integrate an overabundance of behaviour change theories. The TDF can be used to assess implementation issues and inform the design and implementation of behavioural interventions. The original TDF had 33 domains. Cane and colleagues have mapped the TDF on to the Capability, Opportunity and Motivation domains of the COM-B ((221) see Table 19

Table 19). This modified TDF has 14 domains. The modified 14 domain TDF was used to elaborate on the broader capability, motivation and opportunity constructs allowing more intricate explanatory differentiation of the three domains of COM-B during development of the topic guides (221).

Table 19 The Theoretical Domains Framework (TDF) mapped to COM-B(221)

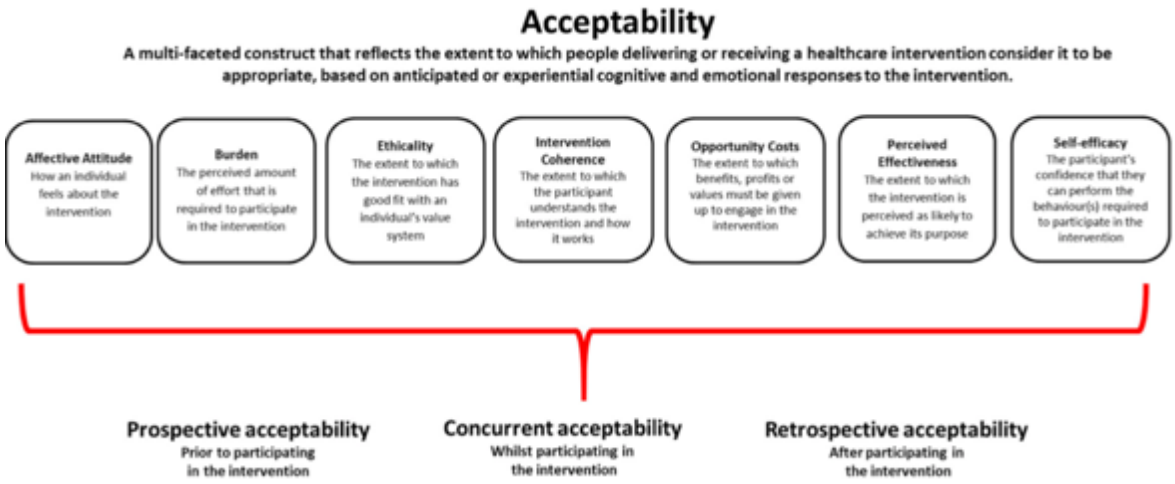
COM-B component		**TDF Domain**
Capability	Psychological	Knowledge
		Skills
		Memory, Attention and Decision Processes
		Behavioural Regulation
	Physical	Skills
Opportunity	Social	Social Influences
	Physical	Environmental Context and Resources
Motivation	Reflective	Social/Professional Role & Identity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

4.11.3.3 The Theoretical Framework for acceptability

Assessing the acceptability of ILAT to both participants and assistants/volunteers was an essential step for the development of the delivery of ILAT by assistants/volunteers within the NHS. The Medical Research Council recommends that acceptability be assessed in the development and implementation of interventions. Where acceptability to participants was low it may have caused resistance to ILAT resulting in poor attendance or compliance with intervention procedures. Similarly, if assistants/volunteers find ILAT unacceptable then intervention procedures may be poorly delivered reducing the fidelity and clinical effectiveness of ILAT. The Framework for Acceptability version 2 (TFAv2) was developed by Sekhon, and colleagues to provide a comprehensive framework of acceptability (222). The TFAv2 has seven constructs that consider acceptability before, during and

after receipt of treatment (see Figure 14). COM-B, the TDF and the TFAv2 were used to inform the development of the topic guides and provided a framework for coding interview responses.

Figure 14 Theoretical Framework of Acceptability version 2 (TFAv2) from Sekohn, et al. 2017 pg. 8 (222)



4.11.3.4 Logic model of ILAT

After the collection of the interviews it was decided to opportunistically code the data to the logic model to further examine the feasibility and acceptability of the assistant/volunteer facilitated ILAT. The logic model codes are presented as inputs, activities and immediate outcomes with hashed numbers representing the logic model components. Appendix 24 shows the list of domains and coding key for COM-B, TDF and TFAv2 within the topic guides.

Table 20 Domains and coding key for COM-B, TDF, TFA and logic model of ILAT

COM- B domains (220)	**TDF domains** (221)	**TFAv2 domains** (222)	**Logic model constructs (see figure 9)**
Capability Psychological (CPs) Capability Physical (CP) Opportunity social (OS) Opportunity physical (OP) Motivation Reflective (MR) Motivation Automatic (MA)	Knowledge (K) Skills (S) Memory, attention and decision processes (MAD) Behavioural regulation (BR) Social/professional role and identity (Rid) Beliefs about capabilities (BCa) Optimism (O) Beliefs about consequences (BCo) Intentions (I) Goals (G) Reinforcement (R) Emotion (E) Environmental context and resources (ECR) Social Influences (SI)	Affective Attitude (AA) Burden (B) Intervention Coherence (IC) Opportunity Costs (OC) Perceived Effectiveness (PE) Self-efficacy (SE)	**Inputs** Manual (#1) Training (#2) Engaged SLT department (#3) Assistant staff costs (#4) Motivated assistants/volunteers (#5) Available treatment room (#6) Treatment materials (#7) Motivated SLT (#8) Motivated people with aphasia (#9) **Activities** Programme management (#10) Case management (#11) Transport to treatment centre (#12) Care needs met (#13) **Immediate outcomes** Reach (#14) Dose delivered per protocol (#15) Treatment fidelity or optimisation (#16) Dose received (#17) **Intermediate outcomes** Expressive language (#18) Generalisation (#19) Communication confidence (#20) Naming, Spontaneous Speech, Receptive Language (#21) Repetition (#22)

Three topic guides were developed; one for participants allocated to the ILAT arm that focused on the acceptability and experiences of ILAT, one for participants allocated to the usual care arm that focused on the acceptability of the trial procedures and finally one for the assistants/volunteers that focused on the acceptability, feasibility and experience of delivering ILAT (see Appendix 24). Topic guides were initially drafted based on the research SLTs own clinical knowledge and experience of delivering ILAT and incorporating the constructs from the COM-B, TDF and TFA, Table 21, Table 22 and Table 23 list the questions from the topic guide and the constructs from COM-B, TDF, TFA v2 and logic model that were being explored.

Table 21 ILAT arm topic guide questions with codes from COM-B, TDF and TFA

Question	COM-B	TDF	TFA	Logic model
How does your communication problem affect your life?	CP CPs OS OP	S MAD BCa E	-	-
How important is it to you that your communication problem improves? Do you think your communication can improve?	MR MA	BR OIG	-	#9
How much Speech therapy have you had before? Did it help you? Would you have liked more speech therapy?	OP MR	-	-	-
What did you think when you first heard about the intensive group therapy? Did you think you would be able to do the group therapy? Did you think the group therapy would help you talk more easily?	MR	BCo G S I ECR	AA B PE SE	#9
Did you enjoy the group therapy? What was good/bad? What was hard/easy? Was there anything you thought would improve the group therapy?	S I	-	AA B IC	#15 #17
Do you think the group therapy helped you to communicate better?	-	-	B PE	#18 #19 #20 #21 #22
Did you feel [insert SLTA/volunteer name] supported you during the therapy?	-	-	AA IC	#11 #13
How confident did you feel about having a go during the group therapy? Were there any things that helped you to feel more confident to try during the group therapy? Did you ever feel uncomfortable or upset during the group therapy?	MR	-	OS MR SE	#9 #16
Would you change how much or how often you attended the group therapy?	-	-	B OC	#15 #17
Did you like being in a group with other people with aphasia?	MR		OS IC AA	#15 #16 #17

Table 22 Usual care topic guide with codes from COM-B, TDF, TFA and logic model

Questions	COM-B	TDF	TFA	Logic model
Did you enjoy being a part of the research? Would you change anything about the research?	-	-	AA B	-
What did you think when you first heard about the intensive group therapy? Did you think you would be able to do the group therapy? Did you think the group therapy would help you talk more easily?	MR	BCo G S I ECR	AA PE	#9
How easy did you find completing the assessments? Were the assessments too much, just right or too little?	-	-	B	-

Table 23 Assistant/volunteer topic guide with codes from COM-B, TDF and TFA

Questions	COM-B	TDF	TFA	Logic model
Tell me about your experience during the ILAT group? What did you enjoy? What did you find challenging? Would you change anything about facilitating the group therapy?	OP OS	S K RId	AA B SE IC	#1 #5 #6 #7 #9 #11 #12 #13 #15 #16 #17
Tell me about the training. Was it too much, just right, too little? Was there anything you wished you had been told during training?	-	S K	IC SE B	#1 #2
Tell me about the supervision? Was it too much, just right, too little? Would you change anything about the supervision?	-	S K	AA IC SE	#10
How many days of ILAT did you facilitate? Was that too much, just right, too little? How many days would you have liked to facilitate?	CP	-	B	#5 #15 #17
Tell me about completing the observation record? Is there anything you would change about the observation record?	CP CPs	S K	AA IC SE	#1 #7 #16

The topic guides for participants with aphasia (ILAT and usual care arm) were developed to reflect the comprehension abilities of the participants in line with the Consent Support Tool (197). Each question can be presented at three different levels. The first level questions are conceptually and grammatically simple and were colour-coded green. These questions were presented with visual prompts and cues. The next level questions were more grammatically and conceptually complex and colour-coded orange and the final level represents the most conceptually challenging and were colour-coded red (see Appendix 24 (223)).

Topic guides for the ILAT arm semi-structured interviews were piloted with a member of the project patient and public advisory group (external pilot). One person with aphasia who had received ILAT and their carer completed a pilot interview and provided feedback on the questions, materials and procedure for the interview. This pilot interview allowed the research SLT to evaluate the completeness and appropriateness of the topic guides and to trial the methods of interviewing participants with aphasia. The pilot interviews prompted the research SLT to create a booklet showing each main question supported by aphasia friendly images with a visual rating scale presented individually on each page (see Appendix 24). This book then formed the basis for the discussion of each question.

It was not possible to complete an external pilot interview for the assistant/volunteer, as the

assistants available were all participating in the trial, or the usual care arm interviews. So, the first interview using these topic guides was used as a pilot (internal pilot). Additional questions were added to the assistant/volunteer topic guide that prompted the assistant/volunteer to consider if they would make any changes to procedures, attendance or the training provided following the first interview. No changes were made to the usual care arm topic guide following the initial interview.

4.11.4 Procedures for semi-structured interviews

The interviews were conducted face-to-face either at the participants home, outpatient clinic, or assistant/volunteers place of work or mutually convenient agreed location. Verbal consent was taken for participation in all interviews (formal written consent was taken as part of consent to participate in the trial see 4.5.2 Consent of Participants). The research SLT completed all interviews. Interviews for participants with aphasia were video-recorded to allow the use of writing, drawing, gesture and images (known as total communication) (224) to be recorded and analysed along with the information given verbally by participants to gain the highest quality data possible (219). Only the audio of interviews with assistants/volunteers was recorded. The results of the Consent Support Tool were used to identify the communication needs and level for each interview (197). The research SLT who was experienced in communicating with people with aphasia, used a variety of strategies to support the participants to comprehend the questions including: breaking down the topic guide using simple sentences with few key words; gesture; using paper and pen to write or draw and using images and pictures as visual prompts and giving extra time (219). The research SLT clarified comprehension of the questions and responses by asking the same question in two different ways, asking clarification questions and also extrapolating ideas which were then confirmed or denied by the participant. The research SLT presented each question from the prepared book, developed following the pilot interview first (see Appendix 24) then moved through the colour coded questions as appropriate. Where open questions proved too difficult to comprehend or the research SLT was unclear about what the participant was attempting to convey closed questions were utilised. The closed questions followed a funnelling technique used in qualitative interview of introducing a topic and asking subsequent questions that narrowed down to the specific areas of interest. For example asking “how does your communication problem affect your life?” followed by questions that helped participants to explore different aspects for example specific social situations, communication partners or daily activities with questions such as “are there any social situations you avoid?” (219,225). In this confirmatory technique participants were also asked confirmatory yes/no questions to ensure accuracy of interpretation and to clarify information given by the participant. For example “so you’re saying that you found …?” These methods were unconventional for the collection of interview data in qualitative research however, to gather the best quality data from participants with aphasia it was necessary to use these techniques to provide clarity and structure (219).

4.11.5 Qualitative analysis

The interviews were transcribed verbatim and notes added to capture any non-verbal communication (writing, drawing, gesture, images etc.)(219). The qualitative interview data was analysed thematically using Framework approach (226) described by Ritchie, et al. (1994)(226). The following six step process was completed:

- transcription;
- familiarisation with the interviews;
- coding;
- developing and applying an analytical framework;
- charting data into the framework; and,
- interpreting the data (227).

This process identified the key issues relating to ILAT for the assistants/volunteers and participants and allowed for description and understanding of their experiences of taking part in the research, including acceptability of the research design and procedures used.

4.11.5.1 Transcription

The assistant/volunteer and ILAT participant interviews were transcribed in batches after each ILAT course was completed prior to the next course commencing to allow the results to iteratively impact the next ILAT course training and procedures. The research SLT transcribed all interviews for participants and assistant/volunteers for ILAT courses 1-3. Transcription for participants and assistants/volunteers was outsourced for ILAT course 4 to allow the research SLT to spend time on activities related to trial completion. All usual care participant interviews were transcribed by the research SLT after completion of the trial as these were not collected until each participant had completed all trial activities.

4.11.5.2 Familiarisation

The research SLT completed all the interviews for participants in both usual care and ILAT arms and for assistants/volunteers which allowed a sense of familiarity with the data. The research SLT also read through all the transcripts prior to beginning coding to ensure familiarity was recent as some interviews had been taken after ILAT course 1 which were completed in December 2017 and analysis was completed in March 2019. Gale and colleagues, (2013) report that having a single researcher conduct, transcribe and analyse the interviews was beneficial to analysis and interpretation (227).

4.11.5.3 Coding

All coding was completed for all three groups of interviews; ILAT, usual care and assistant/volunteer once all the transcripts were available. Codes were selected from within the COM-B, TDF and TFA domains that were determined on developing the topic guides. Interviews were also coded against the components of the logic model (see Figure 9). Transcripts were coded line by line to ensure all data was allocated a code and therefore was included in the analytical framework (227). NVivo was used to code the interviews. At this stage field notes were also coded and added to the collective data in NVivo (215).

4.11.5.4 Developing and applying an analytical framework

After the first 3 transcripts of ILAT participants and assistants/volunteers were complete, the coding system was assessed to determine if any new codes needed adding to or removing from the prespecified set (227). No data was identified that was not able to be coded by the available coding framework so the research SLT applied the predetermined codes as the analytical framework for the remaining transcripts.

4.11.5.5 Charting data into the framework

A matrix was created using a spreadsheet to allow the data from the transcripts to be charted into categories. Charting involved summarising quotes whilst still maintaining the meaning of the data and provided a reference back to the illustrative quotes for each theme (227).

4.11.5.6 Interpreting the data

Once the data from the interviews was categorised themes were identified that examined the pre-determined theoretical frameworks COM-B, TDF and TFA as well as the logic model (228). It became clear as the categories emerged that the finer detailed domains of the TDF were easily summarised into the three domains of COM-B. The additional 14 domains of the TDF were providing an extra level of complexity rather than explanation and so themes were not created for each of these domains but instead they were subsumed into the COM-B themes.

4.11.5.7 Data coverage and trustworthiness

Data coverage was displayed in tables to show how many participants, assistants/volunteers provided data about each theme and to describe how well the data covered the themes.

4.12 Triangulation Methods

The mixed methods approach of the trial allowed the results of the quantitative and qualitative data to be triangulated combining these methods to provide a more complete picture (229) of ILAT

facilitated by assistants/volunteers. This protocol attempted to integrate, weight and understand different perspectives of complex interventions to give a fuller picture of the success and challenges encountered. Triangulation occurred at the point of interpretation once both data sets quantitative and qualitative had been analysed in isolation. The findings were compared and contrasted and assessed for coherence using the Fetters, Curry and Creswell data "fit" constructs; confirmation, discordance and expansion. Confirmation occurred when both types of data confirmed the same findings. Discordance occurred when one type of data was inconsistent or contradicted the other. Expansion occurred when different types of data diverged, expanding or elucidating different aspects of the same phenomenon (230). A fourth construct of silence was added where only one type of data contributed to the finding in line with Farmers triangulation constructs (231).

4.12.1 Data Sources

The key data sources which are summarised in Table 24 were; semi-structured interviews with participants and assistants/volunteers, research SLT field notes/reflections, topics identified in supervision sessions between the research SLT and assistants/volunteers and quantitative data; minutes of ILAT delivered, minutes of ILAT received, minutes of supervision provided, consent-non-consent, withdrawal rates, attendance rates, clinical outcomes (COAST, CAT naming and picture description, TOMs activity and impairment), and fidelity assessment outcomes. For a full list of data sources see Table 24.

4.12.2 Integration and interpretation of quantitative and qualitative data

The logic model, TFAv2 and COMB-B were used to code, sort and integrate all data sources; assistant/volunteer and participant interviews, SLT field notes and reflections and quantitative data. The results of this coding were represented in a joint display table. The themes from the logic model, COM-B and TFAv2 were chosen as the aim was to assess the feasibility and acceptability of ILAT delivered by assistants/volunteers. An assessment of the coherence of the data sources was completed (see Table 47). The quantitative and qualitative findings were then woven together into a narrative discussion around each theme (230).

Table 24 Data sources

Theme	Quantitative data sources	Qualitative data sources
Inputs (Logic model)		
Willingness to participate	Eligibility, reasons for refusal, reasons for withdrawal, attendance, missed sessions	Interview data re: attendance, perceptions of ILAT
Staffing	Recruitment and retention of assistants, volunteers, costs	Interview data, field notes
Accommodation	-	Field notes
Activities (Logic model)		
Training Assistants-volunteers	Attendance	Interview data
Supervision	Time record	Interview data
Transport to treatment centre	-	Field notes, patient comment
Immediate outcomes (Logic model)		
Deliver 30 hours of ILAT	No. minutes received	Interview data
Receive 30 hours of ILAT	Attendance, withdrawal	-
Treatment fidelity	Fidelity assessment data	Interview data, assistants and participants
Reach	Participant characteristics, aphasia severity, identification, recruitment and retention rates	Field notes
Intermediate outcomes (Logic model)		
Severity of aphasia	COAST, CAT naming, CAT picture description, TOM's Activity and Impairment	Interview data
Communication confidence	COAST	Interview data
Naming	CAT Naming	-
Spontaneous Speech	CAT Picture Description	-
Generalisation	TOM's Activity and Participation, CAT Naming, Picture Description	Interview data
COM-B		
Capability	Baseline CAT naming, Baseline CAT picture description, Baseline TOMs Activity, Baseline TOMs Impairment	Interview data
Opportunity	-	Interview data
Motivation	COAST	Interview data
Acceptability (TFAv2)		
Affective Attitude	Withdrawal, Attendance	Interview data, Field notes
Burden	Consent, reason non-consent, Withdrawal, Attendance	Interview data, Field notes
Intervention coherence	-	Interview data
Perceived effectiveness	COAST, CAT naming, CAT picture description, TOMs Impairment, TOMs activity	Interview data
Self-efficacy	Withdrawal, Attendance	Interview data

4.13 Conclusion

This chapter has described the methods for a feasibility study that contains a pragmatic, mixed method, parallel group randomised controlled pilot trial comparing Intensive Language Action Therapy (ILAT) facilitated by therapy assistants/volunteers with usual care which will meet objectives:

- To estimate recruitment rates;
- To assess the most appropriate and acceptable outcome measures to evaluate whether the goal of the ILAT intervention was achieved.
- To assess the feasibility of the randomisation process exploring any delays/difficulties in delivering group therapy in a timely way following randomisation through iterative evaluation of procedures;
- To assess the feasibility of delivering ILAT using therapy assistants/volunteers through an iterative evaluation process informed by field notes and qualitative interviews; and,
- To explore the acceptability of ILAT delivered by trained therapy assistants/volunteers through semi-structured interviews with participants and assistant/volunteers.

The results are reported in chapter five which described the feasibility of the pilot trial and chapter six which described the fidelity, feasibility and acceptability of delivering assistant/volunteer facilitated ILAT.

Chapter Five: Feasibility of the Pilot Trial

This chapter will present the feasibility results of the pragmatic, multi method, parallel group randomised controlled *pilot trial comparing Intensive Language Action Therapy (ILAT) facilitated by therapy assistants-volunteers with usual care following the CONSORT statement for pilot and feasibility trials* (182) *This includes recruitment rates, feasibility of recruitment, randomisation and administration of outcome measures describing difficulties encountered and solutions found through the completion of the pilot trial. The results of the feasibility of the trial delivery are presented before the clinical results as assessing feasibility of conducting the trial was the primary objective. The clinical outcomes are reported in Chapter six.*

(230).

This results chapter addressed objective four which was to determine if it was feasible to evaluate an intervention that targeted conversation and could be intensively and efficiently delivered in a randomised control trial (RCT). The criteria were: a minimum recruitment rate of one participant per month in line with other RCTs in stroke and health research (210); and, a completion rate for the primary outcome of at least 80% in line with other health research trials (211).

5.1 Implementation of pilot trial

The pilot trial was conducted over two hospital sites within one NHS trust as planned. The pilot trial started recruitment in November 2016 with an intention to remain open for 16 months. Recruitment was interrupted by a period of maternity leave and paused from April 2017 until December 2017. Once open again, the final participant was recruited and randomised in October 2018. The total recruitment period was 16 months. All outcome data was completed by February 2019.

5.1.2 Recruitment and participant flow

Figure 15 shows participant flow through the trial. 54 participants were identified with 76.6% (n=43) identified through treating SLT, 20.3% (n=11) identified through Big CACTUS and no participants identified through stroke charities. Of those identified, 50 potential participants were sent invitation letters. Three potential participants had died and it was clear from patient records that one

participant was too unwell to participate. After invitation letters were sent, contact was attempted via telephone. Contact was not established with five potential participants after multiple attempts, six potential participants were not interested, one participant had died and one participant felt too ill to participate. Consequently, 37 participants received an initial home visit and eligibility assessment. Only three potential participants failed to meet the eligibility criteria; one was receiving intensive SLT, more than 2 hours of individual therapy per week and two were too mild for the treatment group on offer at the time of recruitment, no further groups were available as this was the last group being delivered. Thirty four potential participants were approached for consent and five declined; two due to ill health, two due to anxiety and one felt speech was too poor to participate in a group therapy. As a result, baseline assessments were conducted with 29 potential participants. One potential participant withdrew before baseline was completed, due to distress caused by baseline collection. This participant had difficulty acknowledging the ongoing difficulties caused by aphasia and identifying these through the COAST questionnaire caused some distress. Consequently, recruiting 28 people over a 16 month period resulted in a recruitment rate of 1.75 participants per month. Recruitment by centre per month is shown in Table 25.

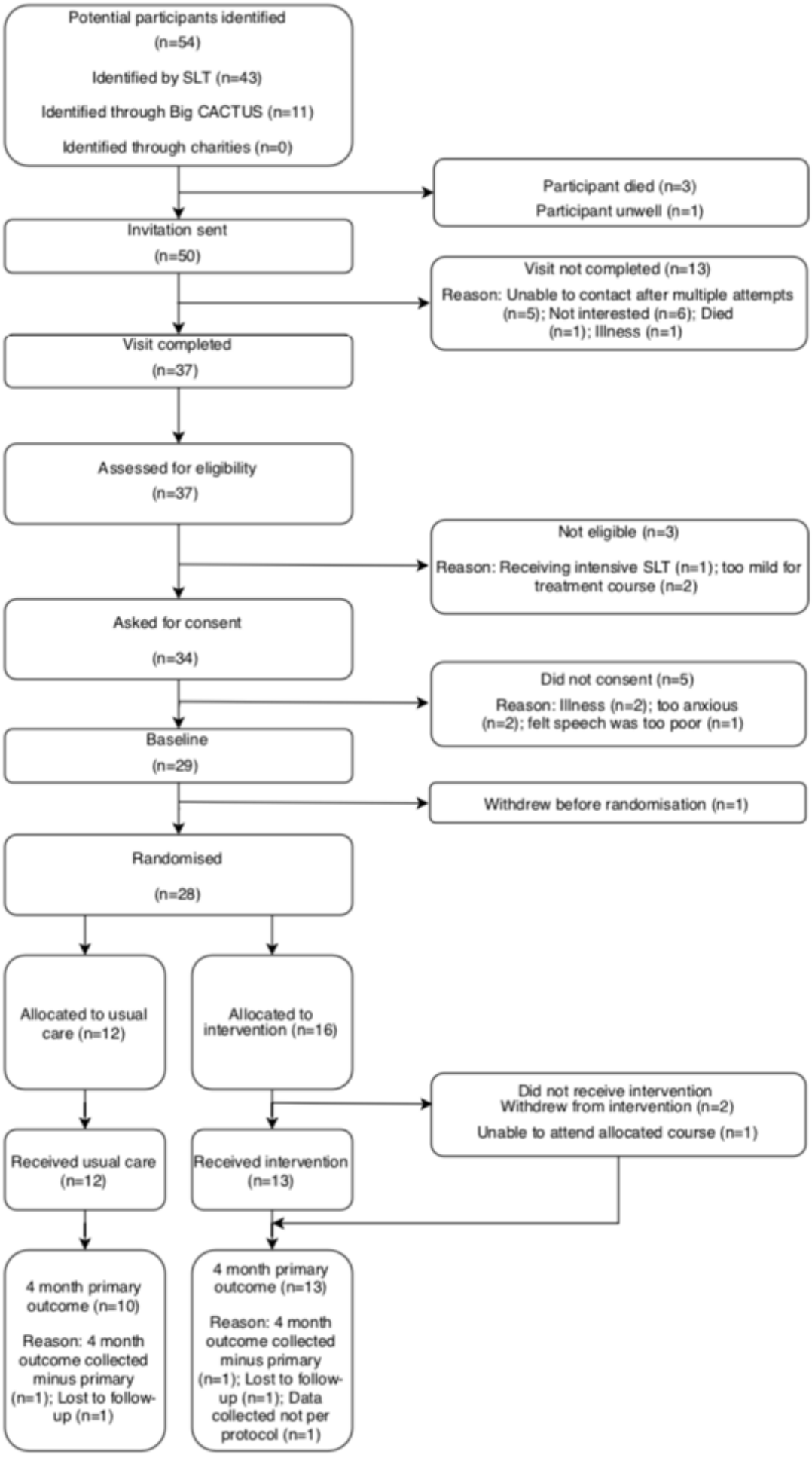
Table 25 Summary of recruitment by centre and month

	2016-2017							2018										
	Nov	Dec	Jan	Feb	Mar	April	May-Dec trial paused	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Total
Centre 1	0	0	2	0	2	2	0	0	3	3	1	0	0	0	0	0	0	13
Centre 2	0	0	0	0	0	1	0	0	0	0	0	0	0	3	8	2	1	15
Total	0	0	2	0	2	3	0	0	3	3	1	0	0	3	8	2	1	28

Recruitment of volunteers was completed through sending invitation letters to all current volunteers within the NHS trust. No volunteers were identified from the current volunteers within the trust. Two volunteers were recruited, consented and participated in the research. One volunteer was identified through a personal approach by a therapy assistant and the other was a relative of a potential participant. Both volunteers facilitated two courses of ILAT. At the time of recruitment of the volunteers there were only two ILAT courses remaining.

Therapy assistants were recruited through the Community and Therapies team at the two hospital sites. Eight therapy assistants were recruited and consented. One therapy assistant did not facilitate any course of ILAT as current pressures in their usual role did not allow participation. Three therapy assistants facilitated one course of ILAT, two assistants facilitated two courses of ILAT and two assistants facilitated across all four courses of ILAT. Five of the therapy assistants were from the Speech and Language Therapy team, two of these assistants had prior training and experience in aphasia and delivering interventions for aphasia. The remaining three therapy assistants were from the physiotherapy team.

Figure 15 CONSORT Flow Diagram



5.1.2.1 Losses following randomisation

Twenty eight participants were randomised: 16 to ILAT and 12 to usual care. The following summarises the reasons for withdrawal. Three participants did not receive ILAT; one was unavailable during the course period and two withdrew from treatment prior to attending any sessions of ILAT. In the ILAT group one participant passed away prior to completing the outcome assessment at 4-months. In the usual care group one participant was lost to follow up as they were unavailable for outcome collection and one participant did not have the primary outcome (Conversational effectiveness rating using Therapy Outcome Measure) as the baseline video file had become corrupted, therefore preventing a comparison rating being completed. Therefore, only 23 participants had a valid and complete primary clinical outcome. This outcome required both the baseline and 4-month outcome assessment to be available in order to complete a rating. Therefore if one of the video files was missing then the rating was unable to be completed. Files were missing due to technical difficulties (video file failed to record or recorded but was unwatchable due to corrupt file), losses to follow-up and data collected not per protocol.

5.2 Timeline of Data collection

Table 26 shows days from consent to baseline collection. There is very little difference across ILAT courses and, overall, the mean was 2 days with a Standard Deviation of 4 days and a range of 0 to 18 days. All participants in ILAT course 1 completed consent and baseline on the same day.

Table 26 Days from consent to baseline

	ILAT 1	ILAT 2	ILAT 3	ILAT 4	Usual Care	All
n	4	4	4	4	12	27
Mean (SD)	0(0)	3 (7)	2(3)	3(4)	1(5)	2(5)
Median (IQR)	0(0)	0(11)	0(5)	2(7)	0(0)	0(1)
Min, Max	0, 0	0, 14	0, 6	0, 9	0, 18	0, 18

Table 27 shows days from baseline to randomisation. A substantially longer number of days were recorded in ILAT course 3 than the other courses with a mean of 57 (SD 72) and a range of 14 to 164 days. ILAT course 4 had a mean of 31.0 (SD 22) and range of 12 to 54 days. ILAT course 3 contained a participant who had aphasia too mild for treatment in ILAT course 2 and who agreed to randomisation in the next batch of participants for the next available ILAT course resulting in an extended period of 164 days between baseline and randomisation (see section 5.3.1 Recruitment for further detail).

Table 27 Days from baseline to randomisation by ILAT course

	ILAT 1	ILAT 2	ILAT 3	ILAT 4	Usual Care	All
n	3	4	4	4	12	28
Mean (SD)	19(18)	24(21)	57(72)	31(22)	24(17)	29(31)
Median (IQR)	21(NR)	24(38)	24(114)	29(40)	27(34)	27(35)
Min, Max	0, 46	4, 43	14, 164	12, 54	0, 46	0, 164

NR = not reportable

Table 28 summarises the number of days from randomisation to ILAT course. ILAT course 1 had a mean of 26 (SD 8) days, course 2 had a mean of 35 (SD 5) days, course 3 had a mean of 43 (SD 7) and course 4 had a mean of 48 (SD was not calculable as all participants were randomised on the same day) with an overall mean of 40 (SD 9) days.

Table 28 Days from randomisation to treatment by ILAT course

	ILAT 1	ILAT 2	ILAT 3	ILAT 4	All
n	2	4	4	2	12
Mean (SD)	26(8)	38(5)	43 (7)	48(NR)	39(8)
Median (IQR)	26(NR)	41(8)	41(13)	NR(NR)	41(13)
Min, Max	21, 32	31,41	37, 54	48, 48	21, 54

NR=Not reportable

Table 29 summarises the number of days from baseline assessment to 4-month outcome by group. There was an overall mean of 5.4 months (170 days) from baseline to assessment.

Table 29 Days from baseline to outcome assessment

	ILAT 1	ILAT 2	ILAT 3	ILAT 4	Usual Care	All
n	2	4	4	4	12	27
Mean (SD)	152(25)	178(36)	199(85)	172(6)	161(24)	170(40)
Median (IQR)	161(33)	178(63)	159(131)	172(NR)	161(31)	161(29)
Min, Max	124, 218	146, 210	152, 327	168, 176	124, 218	124, 327

It was estimated that trial participation would span approximately six months. Table 30 shows the time in months of total trial participation. The mean number of months for trial participation was 5.2

(SD 1.3). Two participants recorded a 7-month total duration in the trial, in each case caused by delayed outcome assessment. One participant recorded a 10-month duration however, this participant was ineligible for participation in the first available ILAT course due to severity of aphasia and chose to wait for the next available group resulting in a delay of 5 months between baseline and randomisation.

Table 30 Total duration of trial participation in months by ILAT course (consent to outcome)

	ILAT 1	**ILAT 2**	**ILAT 3**	**ILAT 4**	**Usual Care**	**All**
n	2	4	4	4	12	27
Mean (SD)	4.3(0.6)	5.2(1.5)	6.2(2.5)	4.5(0.6)	5.1(0.9)	5.2(1.3)
Median (IQR)	4.0(1.0)	5.0(2.7)	5.0(3.7)	4.5(1.0)	5.0(2.0)	5.0(2.0)
Min, Max	4.0, 5.0	4.0, 7.0	5.0, 10.0	4.0, 5.0	4.0, 7.0	4.0, 10.0

5.2.1 Data collected outside of data collection window

One participant's baseline was not completed prior to randomisation, the TOMs was unfortunately missed on the baseline visit and randomisation was completed before this was identified, unblinding the research SLT to treatment arm, therefore this participant was excluded from the analysis. All participants were treated prior to the 4-month outcome being collected. Five participants' 4-month outcome data was collected outside the 4-month window. One participant was collected one day late, one was collected one week late, two were two weeks late and one was three weeks late. These late collections arose due to logistical issues in arranging the collection using blinded Speech and Language Therapy outcome assessors. The blinded assessors were completing the outcomes as additional to their regular working hours which posed some time constraints particularly if an arranged appointment was cancelled as rescheduling was unable to be completed quickly due to this constraint. Batching randomisation across only a period of days (according to numbers of patients who had consented and were of appropriate severity for the next course) meant that all eight outcomes for that course became due across a short period of time. This short timeframe added additional pressure to blinded outcome assessors to complete the same outcomes within a shorter timeframe resulting in the data being collected outside the data collection window. Where randomisation was not batched, outcome collection was more evenly distributed and as a result all outcomes collected in the distributed randomisation protocol were collected on time.

5.3 Changes to trial procedures

Table 31 summarises the difficulties encountered in the trial procedures and the solutions suggested or trialled to amend these difficulties.

Table 31 Changes to trial procedures

Change Number	Trial procedure stage	Problem Type	Solutions
1	Recruitment		
		Recruiting volunteers - No interest from volunteers through invitation to volunteering network within hospital	Names were sought through contacts at the stroke association and from assistants – volunteers were recruited for ILAT course 3 and 4.
		Recruiting participants	Batching participants for severity and location to decrease time taken to form group achieved by:. 1) Moving severity assessment using CAT-naming to screening visit 2) Invitation letters only sent to one site at a time and used discrete recruitment periods for each site.
2	Randomisation		
		Allocation could be guessed for group 2	In groups 3 and 4, Randomisation not completed until a batch of patients' baselines collected (sufficient number to randomise to both ILAT and UC) – allocation concealment maintained following new procedure
3	Forming ILAT courses		
		Participant unavailable for ILAT course	During recruitment a potential range of dates was given and participants were asked to remain available

5.3.1 Recruitment

ILAT was a group therapy delivered to two to four participants. Participants needed to be matched for severity of aphasia, with mild and moderate participants and moderate and severe participants being treated together. Consequently, issues arose with recruitment and allocation. It was possible that participants would be recruited that could not be treated in the next available ILAT course. Recruitment had to be targeted to potential participants who had the severity of aphasia suitable for the next course. In this way, ensuring that all participants recruited could be treated in the next available course. Therefore preventing participants from waiting several months for a treatment

course to be available or being unable to be treated (as happened for one participant recruited for ILAT course 2 but treated in ILAT course 3, resulting in 164 days from baseline to randomisation).

Treating SLTs were asked to provide a guide on aphasia severity allowing the research SLT to target invitation letters to those participants who could form a treatment course. The process of stratification by aphasia severity was refined as recruitment continued and effectively eliminated those unable to be treated in the final treatment group prior to consent being taken.

The mean number of days from baseline to randomisation was 29 days with a range of zero to 164 days. This process of recruitment meant that it took approximately one month to recruit eight participants for usual care and to form a single ILAT course.

5.3.2 Randomisation

A computer generated pseudo-random list with random permuted blocks of varying sizes, created and hosted by the Sheffield Clinical Trial Research Unit was used to allocate participants within this study. Randomisation was stratified for severity, site and due to the number of participants being recruited (only 32), and block sizes were small. Initially participants were assessed for eligibility, gave consent, baselines were collected, randomisation was completed straight after baseline assessments and a treatment group formed as soon as possible following randomisation. Issues arose in ILAT course 2, as randomisation was completed four participants were allocated to ILAT whilst recruitment of the two remaining participants for the block of eight was yet to be completed. ILAT course 2 was the final treatment group for Centre 1 meaning no further ILAT courses were being completed at this centre. Consequently the research SLT became aware that the remaining participants due for recruitment could only be allocated to usual care. It was therefore decided for Centre 2 to assess eligibility, gain consent and complete baselines for all eight participants thus creating a batch before completing randomisation to ILAT or usual care; in this way protecting allocation concealment. There was an imbalance between the randomised groups in some of the clinical characteristics at baseline (TOMS Impairment; CAT Naming, EQ-5D scores) detailed in section5.4 Baseline Data. This is likely a chance occurrence as randomisation procedures were robust and completed correctly.

5.3.3 Forming ILAT courses

In ILAT course 1, one participant was unavailable during the planned two-week group treatment period. This participant was the first person who consented to participate and waited (90 days) between consent and the next available treatment group. For subsequent courses, to reduce the

possibility of unavailability, proposed dates of treatment were given to potential participants at eligibility screening and participants were asked to remain available.

5.4 Baseline Data

The baseline data is presented in this chapter to assess whether participants characteristics were similar between treatment arms using this trial design tested, and allowed assessment of the feasibility of administrating the selected outcome measures which was assessed with completion rates and missing data.

Demographic, stroke history and clinical outcome data for randomised participants by treatment arm are summarised in tables 32-34. Table 32 shows randomised participants had a mean age of 64.4 (SD 11.6), 43% (12 participants) were male and 57% (16 participants) were female and all participants were British. Those in the ILAT arm were slightly older with a mean of 66.7 (SD 9.0) years than those in the usual care arm with a mean of 62.6(SD 14.65) years.

Table 32 Demographics by treatment arm

Demographic Characteristic		**ILAT**	**Usual Care**	**All**
Age (years)	n	16	12	28
	Mean (SD)	66.7(9.0)	62.6(14.65)	64.4(11.6)
	Median (IQR)	65.5(16.0)	63.5(27.0)	65.0(17.0)
	Min, Max	48, 78	40, 84	40, 84
Sex n(%)	n	16	12	28
	Male	7 (44%)	5(42%)	12(43%)
	Female	9(56%)	7(58%)	16(57%)
Ethnicity n (%)	n	16	12	28
	English/Welsh/Scottish/Northern Irish/British	16 (100%)	12 (100%)	28(100%)

Table 33 summarises stroke history. Some differences were found in the time post stroke between the treatment arms. 50% of participants in the ILAT arm were two or more years post stroke whereas just over half (58%) of participants in the usual care arm were between one and two years post stroke. As expected, due the nature of aphasia, the majority of participants (89%) had a stroke lateralised to the left side of the brain and 86% suffered an ischemic stroke. The majority of participants had only suffered one stroke. Slightly more participants in the ILAT arm had severe

aphasia, 31% in the ILAT arm and 25% in the usual care arm. Those with moderate aphasia were matched with 25% in both treatment arms and slightly less participants in the ILAT arm had mild aphasia.

Table 33 Stroke History at baseline by treatment arm

	ILAT	Usual care	Total
Time from stroke*			
1 months to 1 year	4(25%)	3(25%)	7(25%)
1 to 2 years	4(25%)	7(58%)	11(39%)
2 + years	8(50%)	2(17%)	10(36%)
Lateralisation of stroke			
Left	15(94%)	10(83%)	25(89%)
Right	0(0%)	2(17%)	2(7%)
Unknown	1(6%)	0(0%)	1(4%)
Stroke type			
Ischaemic	12(75%)	12(100%)	24(86%)
Haemorrhagic	1(6%)	0(0%)	1(3%)
Not known	3(19%)	0(0%)	3(11%)
Previous stroke			
No	14(87%)	11(92%)	25(89%)
Yes	2(13%)	1(8%)	3(11%)
Aphasia Severity			
Mild	7(44%)	6(50%)	13(46%)
Moderate	4(25%)	3(25%)	7(25%)
Severe	5(31%)	3(25%)	8(29%)

The clinical assessment data at baseline is summarised in Table 34. Generally the baseline assessments were similar across treatment arms and were completed well. Twenty-three out of a total of 27 participants had a complete TOMs impairment rating. There was a 0.5 of a point difference, which is the clinical meaningful difference in favour of usual care arm. Similarly, 23 participants had a complete rating at baseline for the TOMs Activity rating. However, this measure had less than a 0.5 of a point difference between treatment arms. Both the TOMs impairment and activity scales had an adequate completion rate of 85%. Twenty-seven participants had a complete Comprehensive Aphasia Test (CAT) object naming score. Fifteen participants in the ILAT arm had a mean of 24.60 (SD 17.32) and 12 in the usual care arm had a mean of 29.25 (SD 16.41), the overall mean was 26.67 (SD 16.76) which represented a 4.65 (minimum clinical meaningful difference was 4 points) point difference in favour of the usual care arm.

Table 34 Baseline assessment by treatment arm

Assessments			ILAT	Usual Care	All
TOMs Impairment	Rating conversation	n	13	10	23
		Mean (SD)	3.35 (1.18)	4.05(1.19)	3.65(1.16)
		Median (IQR)	3.50(1.3)	4.75(2.1)	4.00(2.00)
		Min, Max	1.00, 5.00	2.00, 5.00	1.00, 5.00
TOMs Activity	Rating conversation	n	13	10	23
		Mean (SD)	3.50(1.31)	3.90(0.97)	3.67(1.16)
		Median (IQR)	3.50(2.50)	4.00(3.00)	4.00(4.00)
		Min, Max	1.00, 5.00	2.00, 5.00	1.00, 5.00
CAT Naming	Naming ability	n	15	12	27
		Mean (SD)	24.60(17.32)	29.25(16.41)	26.67(16.76)
		Median (IQR)	25.00(35.00)	32.00(47.00)	31.00(34.00)
		Min, Max	0.00, 48.00	0.00, 47.00	0.00, 48.00
CAT Picture Description	Connected Speech ability	n	15	12	27
		Mean (SD)	19.50 (18.65)	17.50 (18.00)	18.61(18.38)
		Median (IQR)	10.00(36.00)	18.00(24.8)	16.00(26.00)
		Min, Max	-1.00, 53.50	-5.00, 65.00	-5.00, 65.00
COAST	Self-perceived communication ability	n	14	12	26
		Mean (SD)	51.06 (16.96)	51.33(14.20)	51.18(15.43)
		Median (IQR)	50.13(32.47)	53.75(25.0)	53.75(27.07)
		Min, Max	26.25, 85.00	25.00, 70.00	25.00, 85.00
Carer COAST	Carer-perceived communication ability	n	10	5	15
		Mean (SD)	48.60(20.38)	46.63(10.32)	47.94(17.27)
		Median (IQR)	48.12(23.13)	41.25(17.20)	43.75(20.00)
		Min, Max	12.50, 88.75	37.50, 63.16	12.50, 88.75
EQ-5D score Aphasia	Self-perceived health	n	14	12	26
		Mean (SD)	0.73 (0.21)	0.63(0.32)	0.68(0.27)
		Median (IQR)	0.77(0.29)	0.74(0.43)	0.75(0.38)
		Min, Max	0.31, 1.00	-0.17, 0.94	-0.17, 1.00
EQ-5D score Proxy	Carer-perceived health	n	11	07	18
		Mean (SD)	0.69(0.24)	0.57(0.23)	0.64(0.24)
		Median (IQR)	0.74(0.27)	0.56(0.54)	0.70(0.36)
		Min, Max	0.23, 0.95	0.28, 0.84	0.23, 0.95
Carer QoL	Self-perceived Quality of life	n	10	5	15
		Mean (SD)	75.69(16.11)	74.26(15.48)	75.21(15.35)
		Median (IQR)	79.00(16.10)	77.60(30.0)	77.60(25.90)
		Min, Max	38.10, 92.60	56.70, 92.70	38.10, 92.70

TOMs Impairment/Activity 0(unable to communicate) to 5 (effective communication), CAT naming score out of 38 (higher score = more words named) CAT picture description no ceiling or floor (higher score = more complete/complex language) COAST/CarerCOAST 20 item scale (higher scores= more effective communication) EQ5D Aphasia/proxy 5 item scale (higher scores= better health) Carer QoL 7 item scale (higher scores= better caring situation)

Table 34 also summarises the Patient Rated Outcome Measures (PROM) and the carer rated outcome measures. Generally the treatment arms were similar. The carer COAST was not completed by very many participants as some participants did not have a carer or significant other, and some significant others felt they no longer shared a caring role with the participant and therefore decided not to participate in the study. Again, not all participants had a proxy available who could rate the EQ-5D-5L so only 18 were completed. Only 15 carers consented to participation in the trial. The treatment arms were generally similar at baseline however, for some measures the usual care group had clinically meaningful higher baseline ability than the ILAT arm.

Questions about acceptability of the outcome measures were asked in three usual care arm interviews: all participants reported the assessments were acceptable and that they were not overly burdensome.

Table 35 shows a summary of the response rate for patient rated outcome measures at baseline and 4-month outcome assessment. All PROMs were completed well. There was larger losses to follow-up on carer rated outcomes for the Carer COAST, Carer QoL and the proxy rated EQ5D.

Table 35 Questionnaire item response rates for available questionnaires

			Median % (min, max %) response rate		
Questionnaire	**Time point**	**Total n**	**ILAT**	**Usual care**	**All**
COAST	Baseline	27	100(95, 100)	100(95, 100)	100(95, 100)
	4 months	25	100(95, 100)	100(95, 100)	100(95, 100)
Carer COAST	Baseline	15	100(95, 100)	100(95, 100)	100(95, 100)
	4 months	11	100(100, 100)	100 (95, 100)	100(95, 100)
Carer QoL	Baseline	15	100(100, 100)	100(100, 100)	100(100, 100)
	4 months	11	100(85, 100)	100(100, 100)	100(85, 100)
EQ5D5 Aphasia	Baseline	27	100(80, 100)	100(100, 100)	100(80, 100)
	4 months	25	100(100, 100)	100(100, 100)	100(100, 100)
EQ5D5 Proxy	Baseline	18	100(100, 100)	100(100, 100)	100(100, 100)
	4 months	13	100(100, 100)	100(100, 100)	100(100, 100)

5.5 Usual Care

Data on usual care was collected to understand and describe the comparator group in advance of a full trial. All participants within the trial received usual care with those randomised to ILAT receiving the additional course of ILAT. Twenty-three participants received no SLT as part of their usual care. Only five participants received any SLT during the course of the trial, four received usual care alone and 1 received ILAT and usual care. Of the 5 people who received SLT on average 181 minutes was delivered by a trained SLT and 107 minutes was provided by an SLT assistant. Twenty-two people attended support groups with an average of 232 minutes. Of the therapy delivered on average 153 minutes aimed to improve the aphasia impairment, 93 minutes aimed to provide compensatory strategies to manage communication with aphasia such as training the use of communication devise, and 86 minutes of support for example support to care givers.

Interview data from ten participants revealed variation in how much speech and language therapy (SLT) they felt they received, from 'none at all' to 'quite a lot'. Participants also varied in whether they would have liked to receive more SLT. Interestingly of those who said they had received very little SLT several participants reported they would not have wanted more SLT. Participants also reported the SLT they did receive helped to improve communication.

5.7 Adverse Events

Adverse events are reported in-line with CONSORT recommendations for trial reporting (182). Adverse events were collated and reported to assess whether there were safety or efficacy issues that would require a future safety and efficacy trial rather than a pragmatic trial. Adverse events are summarised according to treatment arm in Table 36. 10 adverse events were identified all related to increased fatigue. No adverse events were assessed as related to ILAT. One serious adverse event was identified (participant died following a further stroke) however this event was also assessed as unrelated to ILAT by the trial steering committee.

Table 36 Summary of Adverse Events overall and by randomised group

	ILAT	Usual Care	Overall
Any Adverse Event	8	2	10
Adverse Event related to treatment	0	0	0
Any Serious Adverse Event	1	0	1

5.8 Summary of validity assessment

The internal validity of the pilot trial was assessed for: adequate generation of allocation sequence; adequate concealment of treatment allocation schedule; inclusion of all participants who were randomised in the analysis; and, adequate blinding as recommended by Schultz, and colleagues to reduce the risk of bias (194). Schultz, et al (1995) state that computer generated randomisation is an appropriate method to maintain allocation concealment (194). Further steps were also taken through altering trial methods to maintain allocation concealment (see section 5.3.1 Recruitment). As far as possible all data from all participants was included in the analysis. Data loss was described in detail in section 5.1.2.1. All available data was included in the analysis in an intention to treat analysis. Blinding of participants or assistants/volunteers was not possible due to the nature of the treatment as it was obvious if participants were receiving an intensive group therapy. It was only possible to blind the outcome assessors to treatment arm. Additionally, the assessor for the primary outcome, TOMs Activity and Impairment, was blind to treatment arm and timepoint (baseline or 4-

month outcome). Assessors reported being made aware of treatment arm on two occasions both from within the ILAT arm.

5.9 PRagmatic-Explanatory Continuum Indicator Summary – (PRECIS-2)

The RCT was designed as pragmatic, multi method, parallel group randomised controlled pilot trial comparing Intensive Language Action Therapy (ILAT) facilitated by therapy assistants/volunteers with usual care. The study aimed to be pragmatic as the overall aim was to assess the feasibility and acceptability of delivering volunteer/assistant facilitated ILAT in the NHS. As such it was important to assess ILAT in as pragmatic as possible, setting, with staffing and including participants that mirrored usual conditions within the NHS. The PRECIS-2 tool was completed to assess the pragmatism within the RCT (187). Figure 16 shows the results of the assessment on the PRECIS-2 wheel. Table 37 summarises the PRECIS-2 criteria, the score for this study and the rationale for that score (a high score indicates a pragmatic approach and a low score indicates an explanatory approach). The results show that the study was towards the pragmatic end of the continuum for most of the criteria of the PRECIS-2 with scores of four allocated for eligibility, recruitment, setting, organisation, and primary analysis. Scores of three were allocated for the flexibility (delivery) and primary outcome. A score of two was allocated to flexibility (adherence). Flexibility for both adherence and delivery were rated toward the explanatory end of the continuum as fidelity was measured and used to change aspects of the ILAT delivery to increase fidelity as the study progressed. This level of monitoring would not be completed in practice so is not pragmatic. However, it was useful in this pilot trial to examine how to maximise fidelity to inform the intervention manual, training and resources required for a future trial. In a future pragmatic definitive trial of assistant/volunteer facilitated ILAT fidelity and adherence would be observed but not controlled in the same way as it was here.

Figure 16 PRECIS-2 wheel

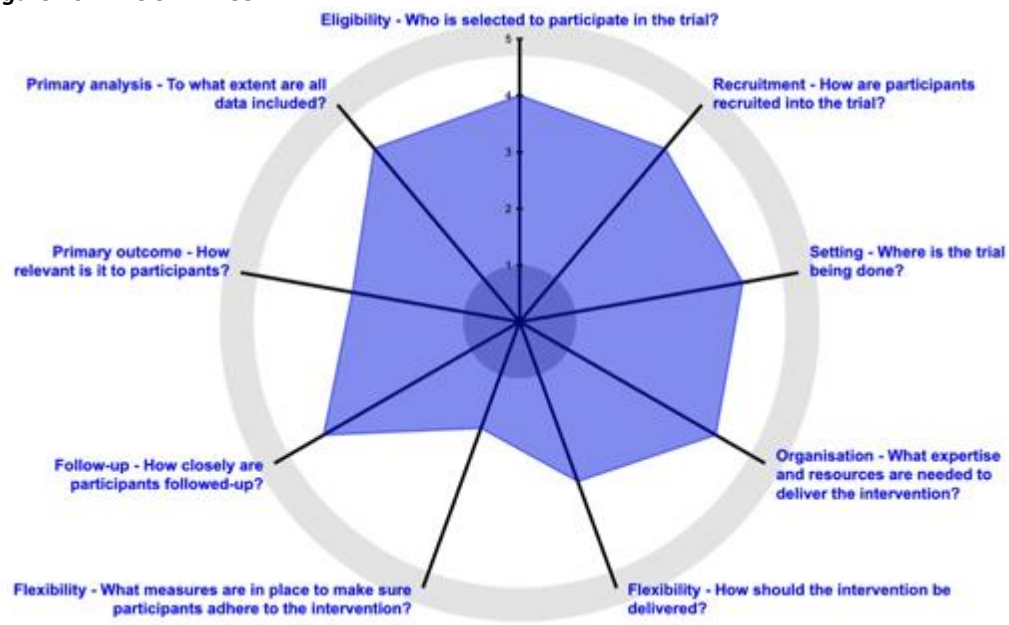


Table 37 PRECIS-2 scoring and rationale

PRECIS 2 criteria	Score	Rationale
Eligibility -to what extent are the participants in the trial similar to those who would receive this intervention if it was part of usual care?	4	Very broad inclusion criteria, only the inclusion of people who had been discharged from SLT services is beyond the scope of usual practice
Recruitment - how much extra effort is made to recruit participants over and above what that would be used in the usual care setting to engage with patients?	4	SLTs identified participants from caseloads, only the inclusion of participants who had been discharged from usual care is beyond the scope of usual practice
Setting - how different is the setting of the trial and the usual care setting?	4	Only a single centre however the setting is a standard SLT department in a general hospital trust
Organisation - how different are the resources, provider expertise and the organisation of care delivery in the intervention arm of the trial and those available in usual care?	4	Additional training was given to deliver ILAT, assistants were those already working in the department, a small increase in assistant time was required
Flexibility (delivery) - how different is the flexibility in how the intervention is delivered and the flexibility likely in usual care?	3	ILAT was delivered in the manner it would be delivered in usual care however, there was an intervention protocol and adherence was monitored and enhanced through training and supervision
Flexibility (adherence) - how different is the flexibility in how participants must adhere to the intervention and the flexibility likely in usual care?	2	Participants were encouraged to participate in the same way as would be expected in usual care. However, fidelity of delivery and adherence to treatment manual were closely monitored and used to improve the delivery of ILAT.
Follow-up - how different is the intensity of measurement and follow-up of participants in the trial and the likely follow-up in usual care?	4	A similar follow up pattern was taken in that an assessment and feedback were given to participants once after completion of the intervention, however the difference was the time point at which this was collected as it was 4-month post randomisation rather than immediately on completion of the intervention
Primary outcome - to what extent is the trial's primary outcome relevant to participants?	3	The primary clinical outcome was the TOMs activity and impairment scales that attempt to rate conversational ability. Improving conversational ability is one of the key goals of people with aphasia.
Primary analysis - to what extent are all data included in the analysis of the primary outcome?	4	Analysis was completed using intention to treat, one participant was excluded post randomisation due to protocol breach.

5.10 Sample size calculation

An indicative calculation of the sample size was completed using the assumptions from a RCT of people with aphasia using similar outcomes using the two primary endpoints (word finding ability and functional conversation) and a key secondary endpoint (patient perception of communicative ability) for a 90% power and a two sided significance level of 5% (211) resulting in a sample size of 95 participants per arm was calculated for a definitive trial. The assumptions for this sample calculation are published in the Big CACTUS protocol (201). There was a definite therapeutic environment and group dynamic that was developed across the course of the intensive massed time spent together resulting in a therapist effect. Delivering ILAT in groups or clusters causes there to be less variability between participant's responses, which then erodes the power to assess true differences between the treatment arms. Also, ILAT requires participants to be grouped by severity prior to treatment further compounding the similarity between participants in each group. Therefore this effect must be accounted for when estimating a sample size to detect an effect. The intra-cluster correlation coefficient (ICC) or the therapist effect describes the degree of correlation between participants due

to the skill of the therapist and also due to the group dynamic. In this study due to the grouping of participants by severity of aphasia the ICC was high at baseline as well as at four-month outcome assessment. Table 38 shows the Inter-cluster Correlation Coefficient (ICC) for TOMs Impairment of 0.328 at baseline and 0.317 at 4-month outcome assessment and TOMs activity as 0.532 at baseline and 0.487 at 4-month outcome assessment. Therefore, using the TOMs activity ICC of 0.487, as it is the primary endpoint, to calculate the inflation factor of 2.46. The inflation factor was then used to update the sample size calculated previously which inflated the ILAT arm sample size to 234 participants whilst the usual care arm would remain at 95 participants. Alternatively, if a therapist effect was also suspected in the usual care arm the ICC could be inflated for both arms resulting in an estimated sample size of 468. The feasibility of recruiting 329-468 participants is discussed in chapter seven.

Table 38 Inter Cluster Correlation between baseline and 4- month outcome for primary outcome

Outcome	No of participants	Correlation baseline	Correlation 4 months
TOMs Impairment	23	0.328	0.317
TOMs Activity	23	0.532	0.487

5.11 Conclusions

Chapter five has presented data on the feasibility of delivering a pragmatic, multi-methods, parallel group randomised controlled pilot trial comparing Intensive Language Action Therapy (ILAT) facilitated by therapy assistants/volunteers with usual care. Feasibility is demonstrated by the following:

- a recruitment rate of at least one participant per month, which was achieved with 1.9 participants recruited per month;
- completion rates for the primary outcome of at least 80%, in line with other health research trials (210); this trial recorded a primary outcome completion rate of 82%.
- determining a feasible method of forming ILAT courses matched for severity of aphasia; in this study four groups were formed taking up to two and a half months to form each group which was feasible;
- tested and refined procedures for the generation and concealment of allocation to treatment arm, analysis of outcome data and blinding of outcome assessors; and,
- the degree of pragmatism within the trial, as assessed through the PRECIS-2 tool; and,
- an ICC (0.487) and inflation factor (2.46) were calculated to determine the sample size of 235 in the ILAT arm and 95 in the usual care arm for a definitive trial (the likely feasibility of this will be discussed in the main discussion chapter).

A more thorough examination of these results including changes to methods and limitations is presented in the final discussion of this thesis in Chapter seven. Chapter six describes the acceptability of delivering assistant/volunteer led ILAT in the NHS and the results of the clinical outcome assessments.

Chapter Six: Delivering Intensive Language Action Therapy facilitated by trained assistants and volunteers in the UK NHS: clinical outcomes, fidelity, feasibility and acceptability

This chapter reports the clinical outcomes of the pilot trial of ILAT facilitated by assistants/volunteers under the supervision of a Speech and Language Therapist (SLT) followed by results of the fidelity assessment of ILAT in order to determine if assistant/volunteer facilitated ILAT was faithfully delivered. Feasibility and acceptability of assistant/volunteer facilitated ILAT and outcome measures are explored. Findings from all quantitative and qualitative data are compared and contrasted using a triangulation protocol and provide insight into the challenges and barriers encountered, and offer solutions to overcome these before a definitive trial.

6.1 Chapter six aims

This chapter addressed thesis aim five which was to determine if it was feasible and acceptable to deliver assistant/volunteer facilitated ILAT in the NHS. Clinical outcome measures were collected to determine the mean difference in change. The specific objectives were to assess;

(1) adherence to treatment protocol as measured by intervention attendance and fidelity assessment; and,
   - feasibility and acceptability of all trial and ILAT procedures through reports from stakeholders.

Four approaches were used to determine the feasibility and acceptability of delivering assistant/volunteer facilitated ILAT:

(1) The fidelity of ILAT delivery was assessed to determine the degree to which it was delivered as intended through the assessment of; the adherence to the treatment manual and the faithfulness of the delivery of ILAT by therapy assistants/volunteers and the completeness of the data collected on the Daily Intervention Log, the accuracy of facilitators completing the Daily Intervention Log, the amount of intervention delivered and received;

(2) Qualitative interviews were used to assess feasibility, acceptability and understanding of ILAT to participants and assistants/volunteers and these were triangulated with clinical outcomes, fidelity outcomes and field notes which provided a more complete picture of acceptability and feasibility; and,

(3) Facilitators and barriers to the success of delivery were identified and solutions were proposed and trialled, were possible, to refine the procedures for delivery in a definitive trial.

6.2 Clinical outcomes results

Clinical outcomes were collected to determine the mean difference in change and the standard deviation to inform a definitive trial. Table 39 summarises the mean difference in clinical outcomes between usual care and ILAT groups at 4 months adjusted for baseline. Twenty-three participants completed a valid conversational rating using the TOM's Impairment scale; with a mean of 3.27 (SD 1.16) in the ILAT arm and 4.15 (SD 1.02) in the usual care arm and an adjusted mean difference of -0.28(-0.79 to 0.23). TOM's Activity rating scale had a mean of 3.5 (SD 1.3) for the ILAT arm, and 4.10 (SD 0.84) in the usual care arm and an adjusted mean difference of -0.24(-0.54 to 0.59). Twenty-five participants completed the CAT object naming subtest at four months, 14 in the ILAT arm with a mean of 24.50 (SD 16.82) in the ILAT arm and 33.45 (SD 14.21) in the usual care arm and an adjusted mean difference of -0.53(-5.54 to 4.49). Twenty-four participants completed the CAT picture description subtest; with a mean of 24.50 (SD 16.82) in the ILAT arm, and 33.45 (SD 18.00) in the usual care arm with a mean difference -1.56(-8.58 to 5.47). Overall, the usual care arm participants performed slightly better across all clinical outcomes. The confidence intervals for all clinical outcomes include zero indicating that there is no difference between the two groups. The clinically meaningful difference for the TOM's activity and impairment is 0.5 of a point. The 95% confidence interval for TOM's impairment does not include this range and the activity confidence interval is just about compatible with the clinically meaningful difference of 0.5. The intra-cluster correlation coefficient (ICC) or the therapist effect was not adjusted for in this analysis as it was not considered necessary when statistical advice was given. This allowed the research SLT to complete the statistical analysis as completing a random effects regression was beyond the capabilities of the research SLT. A rough estimate of the ICC effect was determined to require adjusting the confidence intervals by a factor of 1.3. When this estimate was applied to the confidence intervals it did not change the outcome of the analysis. TOMs impairment remained a mean difference of -0.36 (-1.03 to 0.3) which does not encompass the clinically meaningful difference of 0.5. TOMs activity became a mean difference of -0.312 (-0.70 to 0.77) which does encompass the clinically meaningful difference of 0.5 lending a little more confidence to the results.

Table 39 Mean difference in clinical outcomes between usual care and ILAT groups at 4 months adjusted for baseline

	Treatment group								
	ILAT				Usual Care				*Adjusted mean difference
Outcome	**n**	**Median (IQR)**	**Mean**	**SD**	**n**	**Median (IQR)**	**Mean**	**SD**	**(95% CI)**
TOM's Impairment	13	3.5(2.3)	3.27	1.16	10	4.5(1.8)	4.15	1.02	-0.28(-0.79 to 0.23)
TOM's Activity	13	3.5(2.5)	3.50	1.25	10	4.5(1.3)	4.10	0.84	-0.24(-0.54 to 0.59)
CAT naming	14	24.50(33.0)	24.50	16.82	11	39.0(21.0)	33.45	14.21	-0.53(-5.54 to 4.49)
CAT Picture Description	13	11.0(31.0)	16.07	17.69	11	16.0(24.0)	21.68	18.0	-1.56(-8.58 to 5.47)

*adjusted for baseline, TOMs Impairment/Activity 0(unable to communicate) to 5 (effective communication), CAT naming score out of 38 (higher score = more words named) CAT picture description no ceiling or floor (higher score = more complete/complex language) COAST/CarerCOAST 20 item scale (higher scores= more effective communication) EQ5D Aphasia/proxy 5 item scale (higher scores= better health) Carer QoL 7 item scale (higher scores= better caring situation)

Figure 17 shows there was variability between baseline and 4-month outcome in the ILAT arm with five participants improving by at least 0.5 of a point on the TOMs impairment scale (clinically meaningful difference) whilst three participants remained the same and six participants had a lower rating of 0.5 to 1.0 point between baseline and 4-month outcome. There was more consistency in the results of the usual care arm as seven participants had no change in ratings from baseline to 4-month outcome, two participants had at least a 0.5 point improvement in rating between baseline and 4-month outcome and one participant had a 0.5 point lower rating between baseline and 4-month outcome. Overall, the usual care arm performed better than the ILAT arm although five participants in this arm were at ceiling on this measure.

Figure 17 TOMs Impairment rating at baseline and 4-month outcome per treatment arm

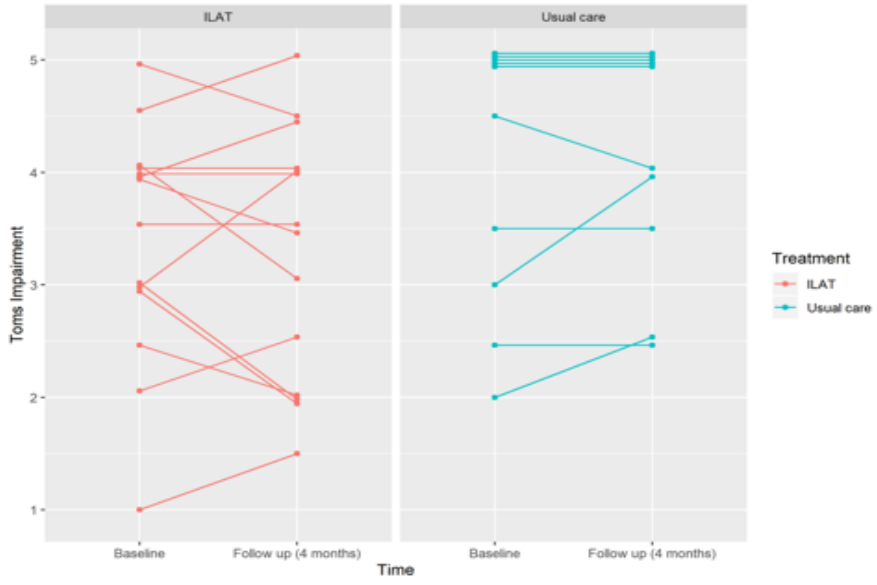


Figure 18 shows four participants in the ILAT arm improved by at least 0.5 of a point on the TOMs activity scale measuring conversation (clinically meaningful difference) whilst five participants remained the same and five participants had a lower rating of 0.5 to 1.0 point between baseline and 4-month outcome. There was more consistency in the results of the usual care arm as six participants had no change in ratings from baseline to 4 month outcome and four participants had at least a 0.5 point improvement in rating between baseline and 4-month outcome.

Figure 18 TOMs Activity rating at baseline and 4-month outcome per treatment arm

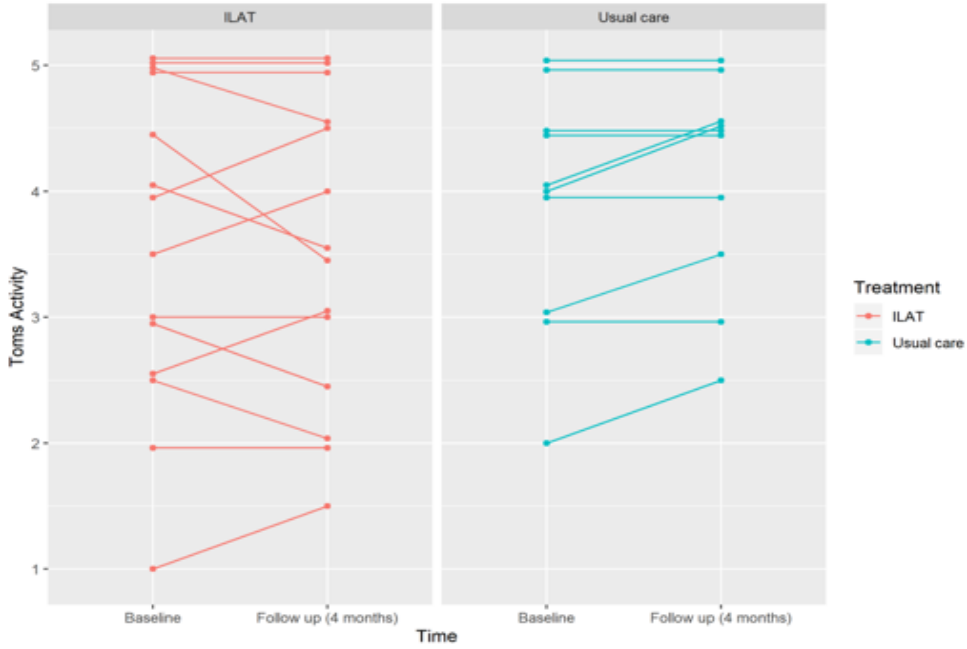


Figure 19 shows eight participants in the ILAT arm improved their naming between baseline and 4-month outcome, whilst one participant remained the same and five participants had a lower score between baseline and 4-month outcome. In the usual care arm four participants showed no change from baseline to 4 month outcome, four participants had an improvement in score between baseline and 4-month outcome and two participants had a lower score at 4 months than at baseline.

Figure 19 CAT object naming at baseline and 4-month outcome per treatment arm

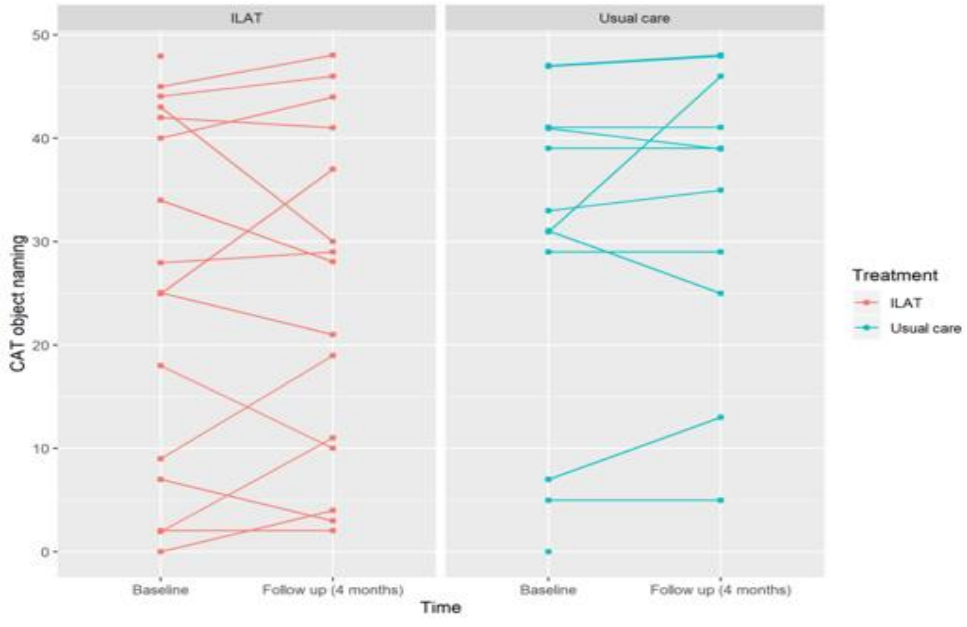


Figure 20 shows seven participants in ILAT improved at picture description between baseline and 4-month outcome, whilst one participant remained the same and six participants had a lower score between baseline and 4-month outcome. In the usual care arm one participant had no change in score from baseline to 4 month outcome, six participants had an improvement in score between baseline and 4-month outcome and four participants a lower score between baseline and 4-month outcome.

Figure 20 CAT picture description at baseline and 4-month outcome per treatment arm

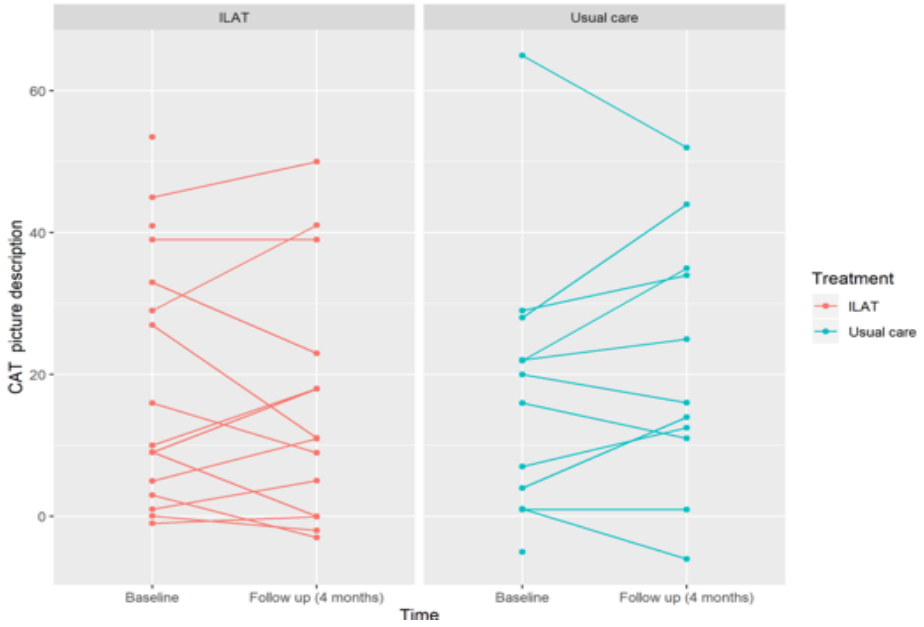


Table 40 shows a summary of results for the patient rated outcome measures at 4-months following adjustment for baseline. As with the previous outcome measures, the COAST showed the usual care arm improved more than the ILAT arm. However, the EQ-5D-5L questionnaire and visual analogue scale (VAS) aphasia friendly version showed a small improvement in favour of the ILAT arm which was confirmed by the proxy questionnaire and VAS of the same scale. The CarerQoL also showed a small change in favour of the ILAT arm.

Table 40 Mean difference in change in Patient Rated Outcome Measures (PROM) between control and treatment (ILAT) groups at 4-months adjusted for baseline

Scale	Total no. of participants	Usual care Group No.	Usual care mean at 4-months	ILAT Group No.	ILAT mean at 4-months	*Adjusted Mean difference (95% CI)
COAST	24	11	69.74	13	63.95	-5.75(-13.76 to 2.26)
Carer COAST	24	11	52.56	13	52.14	0.64(0.24 to 1.04)
EQ5D Aphasia	24	11	0.69	13	0.76	0.13(-0.07 to 0.09)
EQ5DAPhasia - VAS	25	11	69.82	14	74.86	3.30(-11.29 to 17.89)
EQ5D Proxy	13	3	0.52	10	0.70	0.18(-0.05 to 0.41)
EQ5D Proxy-VAS	10	4	55.00	6	69.00	19.13(-9.57 to 47.83)
Carer QoL	10	4	78.07	6	85.87	3.03(-9.68 to15.75)
Carer QoL-VAS	11	4	5.00	7	6.71	1.09(-0.72 to 2.90)

*adjusted for baseline, COAST/Carer COAST 20 item scale (higher scores= more effective communication) EQ5D Aphasia/proxy 5 item scale (higher scores= better health) Carer QoL 7 item scale (higher scores= better caring situation)

6.3 Fidelity Assessment Results

The Fidelity assessment had four purposes, to assess:

1) the adherence to the treatment manual and the faithfulness of the delivery of ILAT by therapy assistants/volunteers;

2) the completeness of the data collected on the Daily Intervention Log (DIL);

3) the accuracy of facilitators completing the DIL; and,

4) the amount of intervention delivered and received.

(for details see section 4.6.6 Fidelity assessment of ILAT).

6.3.1 Adherence

Table 41 summarises the components (see Figure 7 pg. 62 for description of ILAT components) of ILAT that were assessed for fidelity and the scores achieved by ILAT group. Each component represents an essential ingredient for the delivery of ILAT. Overall the components group, card exchange, LAG, stimulus materials and barriers were delivered well. The least well delivered components were intensive and massed delivery and extending participants to work at the upper limit of their communicative competence.

Table 41 Results of Fidelity assessment for ILAT components by ILAT course

Components of ILAT	**ILAT 1**	**ILAT 2**	**ILAT 3**	**ILAT 4**
Group	2	2	2	2
Card exchange	2	2	2	2
Language Action Game	2	2	2	2
Intensive and massed delivery	1	1	1	1
Prompting and feedback	1	1	1	2
LAG complexity and component rules	1	1	1	2
Stimulus materials	2	2	2	2
Barriers	2	2	2	2
Participants working at the upper limit of communicative competence	1	1	2	1
Total Score	**14/18**	**14/18**	**15/18**	**17/18**

Throughout all four courses of ILAT no components of ILAT were missing from the intervention delivered. All ILAT courses were delivered in groups of two to four participants so, all courses were given a score of two on this component. Assistant and volunteer facilitators ensured physical and pragmatic exchanges occurred to maintain the language action embedding component of ILAT and delivered all therapy within the context of the Language Action Game (LAG), therefore, resulting in a score of two out of two on these component across each course.

In contrast, facilitators consistently failed to deliver three hours of therapy in the four hours that participants attended each day (see Table 42). None of the four ILAT courses achieved the target of 30 hours. ILAT course 1 had a target of 27 hours due to a back holiday in the scheduled two weeks of the course. The maximum time delivered was in ILAT course 2 with 21 hours and 49 minutes. Overall, the dose delivered was only approximately two thirds of the intended dose. This resulted in a score of one out of two on this element of fidelity.

Table 42 Number of minutes of therapy delivered by group

Group	**Dose delivered in hours and minutes**	**Target dose**
ILAT 1	19 hours 50 minutes	27 hours (due to Bank Holiday)
ILAT 2	21 hours 49 minutes	30 hours
ILAT 3	20 hours 15 minutes	30 hours
ILAT 4	21 hours 23 minutes	30 hours

The prompting and feedback component of ILAT was identified as an essential component in the faithful delivery of ILAT through the systematic review of the literature and during the development of the initial training package and treatment manual. In ILAT course three, prompting was not identified as a difficulty for facilitators, however the severity of aphasia in this group was moderate to mild and participants had greater independence in completing LAG turns which resulted in fewer prompts being delivered. Observations of this group taken through video recorded sessions showed

participants asked more clarification questions to each other rather than relying on the assistant and volunteer facilitator to intervene. SLT Supervision revealed questions and support required for the assistants and volunteers for this group with mild-moderate aphasia were more in regards to group dynamics and coherence and materials including introducing more game types to maintain interest.

In ILAT courses two and four participants had moderate to severe aphasia so communication breakdown was more frequent and required greater support from the facilitators. Also, in group one, one participant had moderate aphasia that was more severe than those participants in group three. The other participants in group one had mild aphasia so required very little prompting. The more mild participants in group one did not take on the independent questioning that appeared in group three instead leaving clarification questioning to the facilitators. Field notes confirmed this difference in facilitator role during courses comprising participants with more severe aphasia. Supervision for courses comprising participants with moderate to severe aphasia centred around how and when to provide prompts particularly focusing on how long to wait before intervening and also on how to manage participant frustration and anxiety when communication breakdown occurred. Observations of ILAT courses containing participants with moderate to severe aphasia showed many LAG turns required the prompting support from the facilitators. In ILAT course two facilitators tended to ask forced choice questions that included the item the participant was attempting to say, for example “is it a picture of a fish or a dog”; whereas the prompting should be more information gathering such as “is it an animal or a plant” or “do you find this animal in the sea or on land”. The training and treatment manual went through an iterative refinement where issues were identified and solutions were trialled across the four courses. This process is discussed in section 6.4.3.1 Manual and training. Prompts and feedback were consistently scored at one out of two across ILAT courses one to three. As a result of the changes made to the manual and training, assistants and volunteers that facilitated ILAT course four were providing prompts and feedback that adhered to the treatment manual resulting in a score of two out of two.

LAG complexity and component rules also proved to be more difficult for facilitators to faithfully deliver. Again, this component was never omitted however, substandard modelling and delivery of these rules was observed in ILAT course one and two. Interview data and supervision discussions revealed issues were also identified in the understanding of these components and how to accurately record them on the DIL. Additional information to clarify the complexity and component rules was added to both the manual and training material before ILAT course three and this resulted in adequate modelling and delivery of this component in ILAT course three and four.

However, the recording of these components on the Daily Intervention Log (DIL) remained problematic during ILAT course three and further training was given including practice scoring the DIL with scripts that were added to the manual. For full discussion of these issues see 6.4.3.1 Manual and training. Finally, following these adjustments to the manual and training these issues were overcome and recording of these components on the DIL was accurate resulting in a score of two out of two for ILAT course four.

Stimulus materials were appropriately used throughout all ILAT courses. In ILAT course 1, 2 and 3 the need for additional materials was identified and these were created whilst the course was still progressing so did not cause difficulties in the delivery of ILAT resulting in a score of two out of two for all ILAT courses on this component. Barriers were used appropriately in all four courses of ILAT resulting in a score of two out of two for all courses on this component.

Observations revealed that facilitators were not requiring participants to work at the upper limit of their communicative competence as prompts were being provided incorrectly or too soon and in some cases telling participants the word prior to independent attempts. Interview data also confirmed misunderstanding and difficulties associated with the faithful delivery of ILAT for this component, a full discussion of the issues, solutions and their success is reported in section 6.5. Consequently, it was only in ILAT course three that participants were being supported to work at the upper limit of their communication competence. Issues with this component returned in ILAT course four with participants who had more severe aphasia.

6.3.2 Completeness of Daily Intervention Log

Table 43 summarises the completeness of data entered on to the Daily Intervention Log (DIL) by assistant and volunteer course facilitators. The DIL was an essential element of ILAT as it allowed the SLT to remotely supervise and progress participants through the ILAT courses. It was therefore very important to ensure data was both completely and accurately recorded. A description of the issues encountered and the solutions trialled is described in section 6.6 and 6.7. Whilst data completeness was high throughout all ILAT courses, some improvement across the four courses can be seen in the recording of: card sets, (96% to 100%); duration or number of minutes therapy delivered, (98.08% to 100%); appropriateness, (90% to 94%); and, recording that no prompts were given, (94% to 98%). Type of LAG either request or planning was consistently recorded across all ILAT courses (100%). Appropriateness, of participants sentence production, recording was the least well completed component on the DIL. Issues around understanding how to make these responses was identified through both supervision and interview data. ILAT course two contained the most incomplete recording across all DIL components with an average of 6% missing data. Overall, data completeness

improved across the four ILAT courses resulting in an average of 2% missing data or 98% complete in ILAT course three and four. A full discussion of the issues and solutions trialled to improve the data completeness are reported in section 6.5.

Table 43 Daily Intervention Log (DIL) completeness by ILAT course

Components on DIL	ILAT 1	ILAT 2	ILAT 3	ILAT 4
Card set	96%	95%	100%	100%
Type	100%	100%	100%	100%
Duration	98%	92%	97%	100%
Rule complexity	98%	98%	98%	96%
Appropriateness	90%	87%	97%	94%
Prompts none	94%	91%	96%	98%
Average	96%	94%	98%	98%

6.4 Acceptability and perceptions of assistant/volunteer facilitated ILAT

Qualitative interviews were used to assess feasibility, acceptability and understanding of ILAT to participants and assistants/volunteers and these were triangulated with clinical outcomes, fidelity outcomes and field notes which provided a more complete picture of acceptability and feasibility. The findings of the qualitative interviews was not presented separately to avoid repetition and also triangulated data allowed a much richer reporting of the findings than when interview data was reported separately. The results of the triangulation are presented as inputs, activities, immediate, intermediate and longer-term outcomes taken from the logic model (see Figure 9 pg. 88) and the TFAv2 and COM-B themes are integrated throughout. Presenting the findings under the themes of the logic model allowed the exploration of feasibility and acceptability and identified barriers to the success of assistant/volunteer facilitated ILAT. Quotes with bracketed material contain questions and statements used by the interviewer (the research SLT) to clarify or confirm responses from participants where aphasia made the content provided unclear (see section 4.11.1 for detailed description of methods).

This approach provided some interesting findings, for example, there were several instances where participants reported their communication difficulties no longer affected their lives. However, when clarification questions were asked participants identified that there were situations that were still avoided or that they became frustrated when attempting to communicate. It is unclear whether this was due to a misunderstanding of the question or simply not considering the full ramifications of the communication difficulties during everyday life or whether these instances of difficulty, avoidance or frustration were not viewed as having a significant impact on daily life. Regardless, it was enlightening to ask further closed questions which allowed the research SLT to gain deeper insight into the perceptions and opinions of people with moderate-severe aphasia.

6.4.1 Interview participants

Table 44 summarises the characteristics of each interview participant. Participant interviewees had mild-severe aphasia and ranged from one year to eight years' time post onset of aphasia. Six participants had carers who participated in interviews. Ten participants from the ILAT arm and three participants from the usual care arm participated in interviews.

Five facilitators, out of a possible eight, participated in interviews, two volunteers and three assistants. All three facilitators who did not complete interviews facilitated only one session of one ILAT course in ILAT course one or two. Two assistants facilitated three ILAT courses and the remaining assistant and two volunteers facilitated on two ILAT courses. One assistant was an experience SLT assistant who had worked with people with aphasia for 6 years, this assistant took a lead role with ILAT course three and four. Two assistants had no experience working with people with aphasia. The two volunteers had some experience with people with aphasia, one assistant was a stroke survivor that had volunteered previously with the stroke association and one volunteer had supported her own mother who was a person with aphasia.

Table 44 Interviewee characteristics

Category	ID Code	Severity of aphasia	Treatment allocation/ Course facilitated	Years of experience working with PWA/ Time post onset of aphasia
Person with aphasia (carer)	PWA1	Moderate	ILAT	4 years
Person with aphasia	PWA2	Severe	ILAT	3 years
Person with aphasia (carer)	PWA3	Mild	ILAT	3 years
Person with aphasia (carer)	PWA4	Moderate	ILAT	2 years
Person with aphasia (carer)	PWA5	Moderate	ILAT	7 years
Person with aphasia	PWA6	Mild	ILAT	4 years
Person with aphasia (carer)	PWA7	Severe	ILAT	8 years
Person with aphasia	PWA8	Mild	ILAT	1 year
Person with aphasia	PWA9	Mild	ILAT	2 years
Person with aphasia (carer)	PWA10	Severe	ILAT	3 years
Person with aphasia	PWA11	Mild	Usual care	1 year
Person with aphasia	PWA12	Moderate	Usual care	2 year
Person with aphasia	PWA13	Moderate	Usual care	5 years
Facilitator (assistant)	F1	-	ILAT course 1, 3-4	6 years
Facilitator (assistant)	F2	-	ILAT course 1-2	None
Facilitator (assistant)	F3	-	ILAT course 1,2 & 4	None
Facilitator (volunteer)	F4	-	ILAT course 3-4	2 years
Facilitator (volunteer)	F5	-	ILAT course 3-4	1 year

6.4.2 Data coverage

Table 45 and 46 show the content of 18 interviews that could be coded to the TFA, COM-B and the logic model. The greyed out section in Table 46 were themes that were not questioned in the participant interviews and subsequently no data was provided for those themes by participants. Facilitators were interviewed after facilitating each ILAT course therefore, each interview is displayed on a separate row of the table with facilitator ID and the corresponding ILAT course number.

The topic guides were designed with the intention of examining the TFAv2 and COM-B and the coverage of these themes by the data is adequate. The coverage of themes by the participants was good. Facilitators spoke less about the perceived effectiveness, only two facilitators had data that was coded to this theme and three facilitators had data that was coded to opportunity of the COM-B.

The logic model was opportunistically used to code the interview data and as such the data does not have as good a fit with the themes. Some themes have limited coverage such as case management and transport. Some themes had no coverage at all including; engaged SLT department, assistant staff cost, motivated SLT and reach. Only one interviewee talked about care needs.

Table 45 Coverage of interview data for Theoretical Framework of Acceptability (v2) and COM-B themes

	TFA (v2) themes					COM-B themes		
Case	**Affective attitude**	**Burden**	**Intervention coherence**	**Perceived effectiveness**	**Self-efficacy**	**Capability**	**Opportunity**	**Motivation**
F1 ILAT2	●	●	●	-	●	●	●	●
F1 ILAT4	-	●	●	●	●	●	-	●
F2 ILAT 2	●	●	●	-	-	●	-	-
F3 ILAT1	-	●	●	●	●	●	-	●
F4ILAT3	●	●	●	-	●	●	●	-
F4 ILAT4	●	●	●	-	●	●	-	-
F5 ILAT 3	●	●	●	-	●	●	●	-
F5 ILAT4	●	●	●	-	●	●	-	-
PWA1	●	-	-	●	●	●	-	●
PWA2	●	-	-	●	-	●	-	-
PWA3	●	●	●	●	●	●	●	●
PWA4	●	●	●	●	●	●	●	●
PWA5	●	●	●	●	●	●	●	●
PWA6	●	●	●	●	●	●	●	●
PWA7	●	-	●	●	●	●	●	●
PWA8	●	●	●	●	-	●	●	●
PWA9	●	●	●	●	●	●	-	●
PWA10	●	●	-	●	●	●	●	●

Table 46 Coverage of interview data for Logic model subtheme

	Inputs									Activities				Immediate outcomes				Intermediate outcomes			Longer term outcomes
Case	Manual	Training sessions	Engaged SLT depart.	Assistant staff cost	Motivated facilitators	Treatment rooms	Treatment materials	Motivated SLT	Motivated patients	Programme mx	Case Mx	Transport	Care needs	Reach	Dose delivered	Treatment optimisation	Dose received	Decrease in aphasia severity	Improved communication confidence	Improved language outcomes	Generalisation
F1 ILAT2	●	●	-	-	●	●	-	-	-	●	●	-	-	-	●	●	●	-	●	-	●
F1 ILAT4	●	●	-	-	●	-	●	-	●	●	-	-	-	-	-	●	-	●	●	●	●
F2 ILAT2	●	●	-	-	●	●	●	-	●	●	●	-	-	-	-	●	-	●	●	●	-
F3 ILAT1	●	●	-	-	●	●	●	-	-	●	●	-	-	-	-	●	-	-	●	-	●
F4 ILAT3	●	●	-	-	●	●	-	-	-	●	-	-	-	-	-	●	-	-	●	-	-
F4 ILAT4	●	-	-	-	●	-	-	-	-	●	-	-	-	-	-	-	-	-	●	-	-
F5 ILAT 3	●	●	-	-	●	-	-	-	-	●	-	-	-	-	-	-	-	●	●	-	-
F5 ILAT4	●	●	-	-	●	-	-	-	-	-	-	-	-	-	-	-	-	●	●	-	-
PWA1	-	-	-	-	●	-	-	-	-	-	-	-	-	-	-	-	●	-	●	●	●
PWA2	-	-	-	-	●	●	-	-	●	-	-	-	-	-	-	●	●	●	●	●	●
PWA3	-	-	-	-	●	●	●	-	●	-	-	-	-	-	●	-	●	●	●	●	●
PWA4	-	-	-	-	●	●	-	-	●	-	-	●	-	-	●	●	●	-	●	●	●
PWA5	-	-	-	-	●	-	-	-	●	-	-	-	-	-	-	-	●	●	●	●	●
PWA6	-	-	-	-	●	●	●	-	●	●	-	-	-	-	●	●	●	-	●	●	●
PWA7	-	-	-	-	●	-	-	-	●	-	-	●	-	-	-	-	●	●	●	●	●
PWA8	-	-	-	-	●	●	●	-	●	-	-	●	-	-	●	●	●	-	●	●	●
PWA9	-	-	-	-	●	-	●	-	-	-	-	-	●	-	●	●	●	●	●	●	●
PWA10	-	-	-	-	●	-	-	-	-	-	-	-	-	-	-	-	●	-	●	●	●

Table 47 displays the logic model, TFAv2 and COM-B themes and the number of data sources that were coded to each theme and subtheme. Interview data addressed 17 logic model subthemes whilst other sources of data addressed four subthemes. Therefore, interview data and other sources including quantitative data were triangulated for 17 logic model subthemes. Other qualitative sources of data included field notes and observations of ILAT delivery which are summarised in Table 47. Quantitative data sources were available for 16 logic model subthemes. All five TFAv2 themes were addressed by interview data, three themes also had quantitative data so triangulation was completed for these themes. All three themes of COM-B contained interview data and only the construct of capability also contained quantitative data. Therefore, triangulation was completed for this construct.

Table 47 shows 17 out of 29 themes and subthemes in the logic model, TFAv2 and COM-B had both quantitative and qualitative data available which provided: confirmation (n=5), expansion (n=10), silence (n=9), discordance (n=5). The results of the triangulation are presented as inputs, activities, immediate and intermediate outcomes and the TFAv2 and COM-B themes are integrated throughout.

Table 47 Themes and subthemes data sources and convergence coding results

	Number of interview respondents or other sources mentioning each theme					
Themes	**Interviews**	**Other sources**	**Summary interview data**	**Summary field notes**	**Quantitative data**	**Convergence code**
Logic model Inputs						
Manual	7	2 Fidelity data Field notes	Clarification was needed for providing prompting and scoring DIL	Supervision revealed clarification was needed for providing prompts and scoring DIL	Average completeness of DIL ILAT 1 96% ILAT 2 94% ILAT 3 98% ILAT 4 98%	Expansion – findings from three sources addressed different aspects of the theme
Training	7	2 Fidelity data Field notes	Further training was needed for providing prompting and soring DIL	Supervision revealed clarification was needed for providing prompts and scoring DIL	Average completeness of DIL ILAT 1 96% ILAT 2 94% ILAT 3 98% ILAT 4 98%	Expansion – findings from three sources addressed different aspects of the theme
Engaged SLT department	0	2 Referral rates Provided assistant time	-	-	54 people with aphasia referred Assistant time provided by department	Confirmation – two sources of data cover the theme
Assistant staff costs	0	1 Cost provided	-	-	Trust agreed to absorb excess treatment costs for assistants prior to commencing RCT	Silence – only one source of data covered the theme
Motivated facilitators	18	2 Assistant/volunteer rota Field notes	Facilitators were motivated and enjoyed the role and that participants felt well supported	Field notes revealed facilitators were motivated and enjoyed the role	All Rotas were filled	Expansion – three data sources address different aspects of the theme
Available treatment room	8	2 Field notes Minutes of therapy delivered	Rooms were not ideal for size or facility access and that therapy time was lost to comfort breaks	Field notes and interviews revealed some difficulties sourcing treatment rooms and rooms were not ideal for size or facility access	Minutes delivered per ILAT course: ILAT 1 19 hours 50 minutes ILAT 2 21 hours 49 minutes ILAT 3 20 hours 15	Expansion –findings from three data sources addressed different aspects of the theme

					minutes ILAT 4 21 hours 23 minutes	
Treatment materials	7	1 Field notes	More materials were required during ILAT course 1 to maintain interest, introducing a competition game improved participant interest.	Field notes revealed that more materials were required during ILAT course 1 to maintain interest, introducing a competition game improved participant interest.	-	Confirmation - findings from two data sources addressed different aspects of the theme
Motivated SLT	0	1 Field notes	-	Research SLT completed the role of PI, recruiting and supervising all ILAT courses, SLT was highly motivated as this was the SLTs own research project.	-	Silence
Motivated people with aphasia	9	2 Recruitment Attendance records	Interview and quantitative data revealed participants were motivated to complete ILAT	-	Recruitment: 28 participants with aphasia were recruited of the targeted 30 Attendance: 10 participants attended 100% of sessions 2 participants attended 90% of ILAT sessions and 1 participant attended 70% of sessions.	Confirmation – findings from three sources confirmed the theme
Logic model activities						
Programme management	8	2 Field notes Randomisation Facilitator rota	Programme management was important to facilitators and	SLT was able to find rooms, supervise facilitators	4 groups matched for aphasia severity were formed	Expansion – findings from three sources of data addressed different aspects of the theme

			participants.		Facilitator rotas were filled	
Case management	3	2 Field notes Fidelity data	Case management was important to facilitators and participants	SLT was able to progress participants through ILAT using DIL and supervision sessions	Average completeness ILAT 1 96% ILAT 2 94% ILAT 3 98% ILAT 4 98%	Expansion – findings from three sources of data addressed different aspects of the theme
Transport to treatment centre	3	1 Field notes	There were issues with transport and parking issues	SLT had to organise transport for 2 participants in ILAT 2, resolved by car sharing of participants	-	Confirmation- findings from two data sources confirmed the theme
Care needs met	1	1 Filed notes	There were issues with care needs	Field notes revealed facilitators reported time taken to complete comfort breaks was extended due to access to kitchen and toilet facilities	-	Expansion – findings from two data sources addressed different aspects of the theme
Logic model immediate outcomes						
Reach	0	2 Recruitment Demographics	-		Recruitment target met Participants had mild to severe aphasia	Silence – interview findings did not address this theme
Dose delivered per protocol	6	2 Field notes Minutes delivered	Opinion about daily schedule and dose delivered varied among participants and assistants/volunteers	Field notes revealed: facilitators reported challenge of providing tea breaks with distant facilities during supervision, facilitators also reported time taken to settle participants at the beginning of day and at breaks was	Minutes delivered per ILAT course: ILAT 1 19 hours 50 minutes ILAT 2 21 hours 49 minutes ILAT 3 20 hours 15 minutes ILAT 4 21 hours 23 minutes	Expansion – findings from three data sources addressed different aspects of the theme

				challenging during supervision		
Treatment fidelity or optimisation	10	2 Field notes Fidelity data	Concerns about fidelity were raised due to prompting and misunderstanding ILAT rule components Additional data around the requirement for tailoring and optimising ILAT from participants perspective was found	Field notes revealed concerns about fidelity due to prompting and misunderstanding of ILAT rule components, the need for additional materials and game play	Adherence scores from fidelity assessment: ILAT 1 12/18 ILAT 2 13/18 ILAT 3 14/18 ILAT 4 17/18	Expansion – findings from three data sources addressed different aspects of the theme
Dose received	11	2 Minutes received Attendance	Differing opinions from participants about the dose received was found. Facilitators had differing opinions about delivering the intensive dose	-	Minutes delivered per ILAT course: ILAT 1 19 hours 50 minutes ILAT 2 21 hours 49 minutes ILAT 3 20 hours 15 minutes ILAT 4 21 hours 23 minutes Attendance records showed: 10 participants attended 100% of sessions 2 participants attended 90% of ILAT sessions and 1 participant attended 70% of sessions.	Expansion – findings from three sources addressed different aspects of the theme
Logic model intermediate outcomes						
Expressive language	5	4 COAST CAT Picture description TOMs Activity TOM's Impairment	Some participants reported improvement, whilst others didn't	-	TOMs Impairment -0.28(-0.79-0.23) TOMs Activity -0.24(-0.54- 0.59) CAT object naming -	Discordance – data from five sources provided contradictory findings for the theme

					0.53(-5.54-4.49) CAT picture description - 1.56(-8.58-5.47)	
Communication confidence	2	1 COAST	Some participants reported improvement, whilst others didn't	-	There was a slight trend of participants moving from ratings of 0-1 to 2-3 on the COAST rating for confidence question	Confirmation – findings from two data sources confirmed the theme
Naming, Spontaneous Speech, Receptive Language	3	4 CAT naming CAT picture description TOM's activity TOM's impairment	Some participants reported improvement, whilst others didn't	-	TOMs Impairment - 0.28(-0.79-0.23) TOMs Activity -0.24(- 0.54- 0.59) CAT object naming - 0.53(-5.54-4.49) CAT picture description - 1.56(-8.58-5.47)	Discordance – data from five sources provided contradictory findings for the theme
Logic model Longer-term outcomes						
Generalisation	4	4 TOM's activity TOM's impairment CAT picture description CAT Naming	Some participants reported improvement, whilst others didn't	-	TOMs Impairment - 0.28(-0.79-0.23) TOMs Activity -0.24(- 0.54- 0.59) CAT object naming - 0.53(-5.54-4.49) CAT picture description - 1.56(-8.58-5.47)	Discordance – data from five sources provided contradictory findings for the theme
Acceptability (TFAv2)						
Affective Attitude	10	0	Contradictory opinions from different participants was found	-	-	Silence – only interview data addressed the theme
Burden	7	3 Reason for non-consent Withdrawal rate Attendance	Some participants found ILAT tiring whilst others did not	-	Reason for non-consent: One participant did not consent as felt it was too difficult Withdrawal rate: One participant	Expansion – findings from four data sources addressed different aspects of the theme

					withdrew from ILAT before attending course as felt anxious/ wouldn't be able to complete it Attendance records: 10 participants attended 100% of sessions 2 participants attended 90% of ILAT sessions and 1 participant attended 70% of sessions.	
Intervention coherence	7	1 Field notes	Facilitators and participants reported understanding of the intervention	Supervision highlighted components of ILAT that were understood and misunderstood	-	Confirmation –findings from two data sources addressed the theme
Perceived effectiveness	12	5 COAST CAT naming CAT picture description TOMs activity TOMs impairment	Participants and carers reported perceived effectiveness that was discordant with each other and across participants	-	COAST -5.75(95% CI-13.76-2.26) TOMs Impairment -0.28(-0.79-0.23) TOMs Activity -0.24(-0.54- 0.59) CAT object naming -0.53(-5.54-4.49) CAT picture description -1.56(-8.58-5.47)	Discordance - data from six sources provided contradictory findings for the theme
Self-efficacy	11	2 Withdrawal Attendance	Facilitators and participants felt willing to complete the intervention however, some elements were more challenging and required additional experience to master	-	Withdrawal: One participant withdrew from ILAT before attending course as felt anxious/ wouldn't be able to complete it Attendance: 10 participants attended 100% of sessions 2 participants attended 90% of ILAT sessions and 1 participant attended	Confirmation – findings from three data sources confirmed the theme

					70% of sessions.	
COM-B						
Capability	12	4 Baseline CAT naming Baseline CAT picture description Baseline TOMs activity Baseline TOMs impairment	Participants were eager to take part but had some reservations about capability		COAST -5.75(95% CI-13.76-2.26) TOMs Impairment -0.28(-0.79-0.23) TOMs Activity -0.24(-0.54- 0.59) CAT object naming -0.53(-5.54-4.49) CAT picture description -1.56(-8.58-5.47)	Confirmation – findings from five data sources confirmed the findings for the theme
Opportunity	8	0	Participants were often limiting their own opportunities to communicate by avoiding situations or people		-	Silence
Motivation	12	2 Recruitment Attendance records	Interview and quantitative data revealed participants and facilitators were motivated to complete ILAT	-	Recruitment: 28 participants with aphasia were recruited of the targeted 30 Attendance: 10 participants attended 100% of sessions 2 participants attended 90% of ILAT sessions and 1 participant attended 70% of sessions.	Confirmation – findings from three sources confirmed the theme

6.4.3 Inputs

6.4.3.1 Manual and training

Facilitators attended training no longer than two weeks prior to delivering each ILAT course. Training was attended by each facilitator whether they had attended training and delivered ILAT in a previous course. The manual was used to support training and was a reference for facilitators during ILAT delivery. The manual included paperwork for recording the achievement and progression of participants through the ILAT course in the form of the Daily Intervention Log (DIL). Interview data showed that facilitators that the training and manual had not prepared them for facilitating ILAT

"I think reading through the manual it made it sound very complicated compared to doing the actual thing, but that might be just how I interpreted it or just the wording of it or something...When we did it it helped showing what we were doing it was actually was straight forward. (F2)"

"Like at the time, I was like "ah okay, I understand it, I get it", but until you actually do it, you don't know (F5)"

Interview data and observations recorded in field notes identified several problems in understanding the components of ILAT and its delivery by facilitators and hence the feasibility of having ILAT delivered by assistants and volunteers:

b. the integrity of the clinical data collection was compromised by an inflexible interpretation of the carrier phrase by some facilitators. Some facilitators were enforcing the use of prescriptive carrier phrase 'Do you have…?' and not encouraging or rewarding variants of this phrase;

"For instance, 'You might have this one'…I know it might not be 'have you got a?', or 'do you have?'... For me that's a carrier phrase… as long as it's a combination, you know, don't knock him down for that, please tick that box and it frustrates me (F1)."

c. intervention fidelity was compromised by misunderstanding of the prompts, including clarification questions, and feedback provided to participants by facilitators and thus its recording on the DIL .

Yeah, people have got slightly different opinions on how to mark it (F2)"

There was confusion about what each prompt was (semantic and phonemic) and also difficulties in generating clarification questions

"*Encouraging people when they are stuck is quite hard, how many ways can you describe something without giving it away (F3)?";* and,

d. the recording of appropriateness ratings was inconsistent between facilitators resulting in either an under or over representation of participant progress which hindered the supervising SLT from setting appropriate targets and rules for subsequent ILAT sessions.

"…when he was doing really, really well, he was giving, you know, a complex grammatical sentence, when he was giving more detailed descriptions. Whereas when I'm looking at how other people mark that, they've just put a two word phrase, And he's more than a two word phrase...Yeah, people have got slightly different opinions on how to mark it (F1)"

e. Observation and supervision identified that the integrity of the clinical data collection was also threatened due to facilitators confusing the participants DILs and writing another participant's scores on the wrong DIL.

f. Field notes revealed that facilitators found completing the DIL in groups with four participants particularly were aphasia was moderate to severe burdensome. Fidelity assessment confirmed this finding as DIL completeness was least well completed at 94% in ILAT course two where there were four participants with moderate to severe aphasia.

It was evident very quickly during ILAT course one that facilitators favoured one version of the possible three DILs they were asked to trial. Fidelity assessment findings of DIL completeness showed that facilitators DIL completion improved following each round of training and ILAT course.

6.4.3.2 Engaged SLT department

The SLT department was well engaged in the delivery of ILAT with treating clinicians providing a steady stream of participants for eligibility assessment. Staffing rotas for the ILAT courses showed assistants were released from regular duties to support ILAT and additional hours were paid to assistants where required. There was silence from the interview data for this theme.

6.4.3.3 Assistant staff costs

No interviews discussed assistant and staff costs. The NHS trust signed an agreement during the application for funding the study to cover these costs. The costs for releasing assistant time were not funded by the research grant as they were excess treatment costs. The trust decided in this case to absorb this cost, releasing staff within their usual working hours and paying some assistant staff additional hours to facilitate the ILAT courses. Assistant staff were released from across the

community and therapies department to meet the needs of the project resulting in five assistants from SLT and two assistants from physiotherapy participating in the study. As the courses progressed, and in particular during ILAT 3 and 4 a single assistant was released to champion the project and 2 volunteers were also recruited further relieving the burden of staff resource. This shows that the SLT department in which the ILAT programme was delivered was very engaged and supportive of delivering ILAT, demonstrating feasibility of delivery in this NHS trust.

6.4.3.4 Motivated assistants/volunteers

Facilitators were motivated, as demonstrated by attendance at sessions as the rota required. Interview data revealed facilitators felt a sense of pride in taking responsibility for the facilitator role and that the role was challenging and rewarding demonstrating the role was acceptable to facilitators.

"It was really nice to have that position. For you to say right use your skills in this group, that was great (assistant). (F1)"

Supervision sessions revealed that assistants had more experience and tended to take the lead through allocating responsibilities, supporting volunteers and intervening when it was felt the volunteers were not adhering to the treatment protocol.

"Um, I feel like I was pushing both of them (participants) more when I was cueing than when I was sat here, and then I found myself jumping in… And sometimes I did just zip, but I felt like with me not helping, they weren't getting the cueing. (F1)"

Volunteers also sought support and clarification from assistants.

"*I double checked with her (assistant) before I did it again, just to make sure … And I looked up how she'd done it on the previous one. (F5)"*

Assistants felt a sense of pride and achievement when they could see the volunteers using the prompting and feedback correctly

"So I was well chuffed, that they (volunteer) was really getting the hang of it.(F1)"

Interviews also found that facilitators felt like they were learning with the participants.

"Until you've done it a bit more its learning for the participants and the facilitators (F3)".

Interviews revealed that participants found facilitators to be helpful, supportive and encouraging and that this motivated continued participation in the ILAT course demonstrating that participants found it acceptable to have assistants and volunteers facilitating ILAT.

"(a volunteer) did take me aside just before I left on one of the days just to have a chat about how I was feeling and things in general and a bit of her journey (facilitator was a stroke survivor) to give me an idea on she understands what I'm going through sort of thing. I did find that really, that was a real big help to me (PWA8)"

The motivation of facilitators was confirmed by rotas being filled and sessions being attended by facilitators. Across the four ILAT courses all facilitator's sessions were covered even when short notice illness occurred another facilitator was willing to fill the gap. Facilitators also travelled between hospitals to ensure all sessions were covered.

Interview data coded to the Capability theme of the COM-B revealed that facilitators felt capable facilitating ILAT and completing the DIL.

*"Yes I feel like I kind of just know how to do that (*giving prompts and feedback*) going on the wards and stuff talking to patients. I don't feel out of my depth on that (F2)"*

"I definitely the tick boxes are really good as it goes round there is no way you can write everything down or whatever. And like the format of it all was easy to use (F2)."

Interview data coded to the theme self-efficacy from the TFAv2 gave further insight into the facilitators perceptions of their own ability to facilitate ILAT showing that experience increased the facilitators confidence in their capabilities.

"Yeah by the end I'd got the hang of it yeah (F4)"

6.4.3.5 Available treatment room

Field notes documented some difficulties were encountered with treatment room availability and interviews revealed dissatisfaction in the size of the treatment rooms and access to kitchen and toilet facilities.

"*The small group, room and you were (gesturing jumping from side to side) but everyone you have to have what you have (PWA4)."*

Toilet and kitchen facilities were located through an ID card-controlled door limiting access to the facilities to only when accompanied by a staff member. Interview data revealed this had an impact on time management during the ILAT course as rest breaks were extended by the inconvenient

location of facilities, demonstrating the importance of accommodation as a factor in whether ILAT is feasible to deliver. The assessment of minutes of therapy delivered revealed that only approximately two thirds of the intended dose was delivered and inconvenient facilities may have had an impact on the ability to deliver the intended dose. For the final ILAT course the facilities were more easily accessible and the minutes of therapy delivered increased by one hour and eight minutes however this was still just over eight hours less than the intended dose.

6.4.3.6 Treatment materials

Treatment materials were made available following the methods outlined by Difrancesco, Pulvermuller and Mohr, (57). Field observations noted further tailoring of treatment materials was completed by facilitators once participant interests were identified. Interview data revealed facilitators were surprised at the speed which participants completed materials and required new materials to maintain interest and participants reported some boredom and difficulty thinking of new things to say on repeated treatment materials.

"…we'd had the same pictures time and time and time and in two weeks we knew the pictures off by heart (PWA6)"

Where other participants found the repetition acceptable

"He got bored because it was the same pictures over and over again but I didn't, I didn't mind (PWA9)"

Creating additional treatment materials related to individual participant interests was time consuming. In this case an assistant took on the role of creating additional resources during ILAT course one and two. The additional categories of general interest which included sematic categories such as breeds of dogs and different types of flowers as well as activities of interest such as pictures depicting fishing or playing golf. These tailored sets of cards were also general enough that other ILAT courses utilised these sets. A further set of everyday activities was created for the final ILAT course as the participants aphasia severity required a set that was more easily described than the previous courses. Whilst the initial creation of these cards was time consuming the resource improved the acceptability of ILAT for participants. For the theme treatment materials the triangulation of the two data sources confirmed the findings.

6.4.3.7 Motivated SLT

In this case the SLT supporting the ILAT courses was the researcher who of course was highly motivated to complete the intervention. However, this would not be the case in a definitive trial but

instead SLTs would consent to participate and would be expected to complete the research tasks following training, using the treatment manual. Only one source of data, field notes, provided findings for the theme motivated SLT.

6.4.3.8 Motivated patients with aphasia

Prior to attending ILAT, interview data coded to the theme affective attitude (TFAv2) revealed that participants varied in their feelings and expectations about ILAT from;

(2) excited and hopeful,

Hopefully, what everybody says how there how but I would like to but its… yes, will continue to improve, hopefully, hopefully (PWA4)

(3) to anxious,

"(Did you feel worried about doing the group therapy?) Yea …(Was it because you didn't know really what would happen?) Yea (PWA1)"

(4) and even sceptical

"I thought you was trying to wound me up (PWA6)."

Quantitative data also confirmed that some participants were anxious about attending an intensive group therapy as three eligible participants reason for non-consent was recorded as anxiety and one participant withdrew from the intervention prior to attending any sessions of the ILAT course stating anxiety as the main reason for withdrawal.

Confirmation was also found as facilitators viewed participants as motivated, reporting examples of participants exerting maximal effort to achieve LAG turns refusing support from facilitators. Facilitators reported it was rewarding to see participants making effort to achieve their goals within ILAT. Participant interviews revealed several themes surrounding enjoyment of ILAT, determination and expectation that ILAT would improve their communication.

"I was going to try everything I could to help. If it was going to help me I was going to, you know I was going to try it (PWA7)"

Attendance records revealed ten participants attended 100% of sessions, two participants attended 90% of ILAT sessions and one participant attended 70% of sessions. Reason for non-attendance were attending appointments (n=1) and illness (n=2) confirming the qualitative findings that participants were motivated to attend the intensive course.

Baseline clinical outcomes and meeting the eligibility criteria showed that participants had the communicative capabilities to complete a course of ILAT. Interview data coded to Capability (COM-B) and Self-efficacy (TFAv2) revealed participants felt eager to attempt ILAT

"Very very… (indicating positive wanted to do it) (PWA5")

however, some reservation about whether it was achievable and they viewed themselves as capable were expressed by some participants.

"No I just thought it would be one of these things you come one day and then won't come no more (PWA6)"

"Um me first thoughts were I'm not going to be able to do it every day, because I get tired, me initial reaction was this is going to be a long two weeks (PWA8)".

On the whole participants were willing and motivated to complete the ILAT course.

6.4.4 Activities

6.4.4.1 Programme management

Recruiting facilitators to fill the rota and run an ILAT group was completed for four courses of ILAT. However, field notes recorded delays in commencing ILAT course two due to difficulties finding enough facilitator time to fill the rota. Difficulties were encountered in recruiting volunteers, only two volunteers were recruited and no volunteers were recruited at one hospital site. No volunteers expressed an interest in participating in the facilitator role from the existing volunteers within the NHS trust. ILAT one and two had a rota with six assistants completing the course. This created some difficulties in continuity of care and handover of participant progress between sessions. Three issues were identified through, field notes and interview data, regarding problems with continuity of care and are factors to consider in the feasibility of delivering ILAT:

- Facilitators were unable to meet between sessions and the rota did not allow for facilitators to overlap between sessions to give a detailed handover of participant progress. This resulted in facilitators reporting a lack of clarity about participant previous progress and also impacted understanding of how to apply prompts and rules set by the SLT for the session;

- Different facilitators was reported to impact on the participants.

"They are a little more at ease if it's not two total strangers everyday"; demonstrating changes in facilitators is not particularly acceptable to people with aphasia (F3)

- Lack of hand over between facilitators prevented the communication of general well-being particularly regarding participant fatigue between facilitators of sessions.

"…that had a massive effect on how they performed throughout the day. And because it obviously is quite hard going obviously we had that concern with the first one where she kind of like deteriorated a bit. So if you went into on the first day you would assume that was what she is normally like. I think kind of just monitoring their general (wellbeing), and like I say the fatigue, like they did really well in the morning but fatigued throughout the day (F2)

Programme management also encompassed forming the treatment courses, which proved feasible as evidenced by the recruitment and retention of enough participants to complete four ILAT courses.

6.4.4.2 Case management

Case management included all supervision and support provided by the SLT to the facilitators during the completion of the four courses of ILAT. Supervision was completed after each session by the SLT. Interview data revealed that supervision was considered adequate and that one supervision session a day was the preferred amount.

"Yeah useful, like just to kind of know a) you were doing it right and b) just to kind of feedback how they were doing to you and for you to say right work on this, this and this …(F2)."

The research SLT was able to adjust materials and alter the LAG rules to progress participants through the course of ILAT. Observations of video recorded ILAT sessions revealed that this progression was clinically appropriate. The research SLT felt it was feasible to deliver ILAT using the supervision model.

During ILAT course one the average supervision session lasted 26.6 minutes, by ILAT course four the average supervision session lasted 15.3 minutes. Supervision was an important part of making ILAT feasible for assistants and volunteers to deliver, and to be an acceptable role to them.

6.4.4.3 Transport to treatment centre

Field notes recorded travel to the treatment centre was problematic for two participants in ILAT course two. Interview data confirmed transport issues by identifying dissatisfaction with lack of parking at the treatment centre and complicated payment machines

"I didn't like having to mess about with the carpark like (PWA8)".

Interview data coded to the theme burden (TFAv2) also revealed that travel was tiring for some participants

"It was … very tiring. Oh it was with the travelling and going all the way … and it was tiring (PWA3)".

It was generally feasible to transport participants to the treatment centres during this trial although parking difficulty and fatigue through travelling could be problematic for some.

6.4.4.4 Care needs met

All participants were independent with care needs during the four ILAT courses. Interview data highlighted that one participant had to wait for facilitators assistance to access the wheelchair accessible toilet facilities were located behind an ID badge controlled door resulting in break times being extended. One participant reported frustration that she had to wait for a facilitator to collect lunch from the kitchen which was only accessible through an ID badge controlled door.

"…because not being a member of staff or being allowed anyway I couldn't go into the kitchen myself …by the time it got to twelve o'clock I was starving but I couldn't … go and get it (PWA9)".

This further highlights accommodation and facilities as a factor in the feasibility of delivering ILAT.

6.4.5 Immediate outcomes

6.4.5.1 Reach: eligible patients offered ILAT

Participants with the full range of aphasia severity from mild to severe were treated in the four courses of ILAT. All identified and eligible participants were offered a course of ILAT. One participant was unable to attend the allocated ILAT course due to traveling plans, and two participants withdrew from ILAT course four prior to attending any sessions; one participant gave no reason and one stated anxiety about participation as reason for withdrawal. It was feasible to offer ILAT to people with aphasia. Interview data was silent on this theme as interview findings did not address the reach to eligible patients.

6.4.5.2 Dose delivered per protocol

Table 42 shows the number of hours of ILAT delivered per ILAT course only two thirds of the intended dose was delivered. Interview data and field notes confirmed that additional time was taken to settle participants at the beginning of the session and that breaks were extended by inconvenient facility arrangements.

"*there was only 2 of them (facilitators) and bless them they were trying to dish everything out in between everyone else trying to talk (PWA9)".*

This once again demonstrates the impact of accommodation on the feasibility of delivering ILAT.

Interview data highlighted that facilitators and participants acceptability of the structure of the ILAT sessions varied. Some participants felt the breaks were appropriate.

"You have to concentrate a bit more (laughter) But We did get a break so I think that did help but you do (get tired) (PWA2)".

Where other participants would have preferred to take less breaks and shorten the overall duration of the ILAT sessions.

"That coffee in the middle .. I don't personally drink tea and coffee all the time, … um but I think so by the time you've made the coffee and you've sat down and their talking and chatting then you've got to say right that's it now we've got to get back to it maybe just a slightly shorter day. Like I say that last hour I was ready for going (PWA8)"

Facilitators felt the structure allowed for the management of participant fatigue.

"I think they were definitely due a break when the timing schedule was good. As they were showing signs of fatigue (F5)."

Interview data revealed that facilitators considered break times to be essential in supporting group cohesion and reducing anxiety in participants.

"Even like that first week especially once they've got to know each other, after they've had the breaks and that, got to know and got relaxed with one another, then they really started helping each other out which was great to see (F2)"

"*The lunch time was so important to socialise and when you socialise you can relax then we could do more when we were more relaxed with each other (F5)."*

In terms of the acceptability of the intensity of delivery interview data showed opinion between participants differed. Some participants reported they found the 2 day break over the weekend was difficult causing a disruption in progress which caused a regression in progress for 1-2 days after the break,

"*second week first day not very good then clicked in then and then it went cracking (PWA2)"*

Interview data for the TFA (v2) theme burden, revealed that overall participants found the intense, massed delivery of ILAT tiring;

"The second week and on the first day pooped, pooped (PWA2)"

"Um me first thoughts were I'm not going to be able to do it every day, because I get tired, and four hours even though it was in the middle, my first, first my umm first thing in the morning is my best time, as the day goes on I get more tired(PWA8)."

Interview data showed the massed nature of ILAT, 3 hours a day, divided participants with some participants reported the intensity was too much and less days or more distributed ILAT would be preferential

"Maybe every other day … maybe the full 2 weeks a bit too much I don't know (PWA8)."

and others reported two hours would have been preferential.

"…which meant the last hour from one 'til two, I would say I would rather have carried on and had the last hour with lunch and just gone afterward. Or not have the coffee break and go straight into lunch. It was only that last hour really (PWA9)."

Or that the dose was too much

"(Would you have liked it to be less?) Yea, probably (PWA1)".

Interview data coded to the TFA(v2) theme intervention coherence, revealed participants understood the importance of the intensive, massed dose of ILAT

"*Maybe every other day, or have a day off in between, but then the idea of intense is to keep at it (PWA8)."*

Conversely, the interview data also revealed that the delivered dose of ILAT was acceptable to some participants,

"err I don't think I would I, I did every day (PWA7)"

"he actually surprised me I thought it would be too much for him but he did it (carer for PWA5)"

where other participants would have liked to receive more ILAT despite reporting feeling tired

"I would say I, I would like to be a bit a bit more (PWA3)"

"Four hours isn't long enough. We started, there was tea break, we started, dinner, then it was time to go. If it were just another half an hour maybe (PWA6)"

Still others stated longer days would have been beneficial;

"…think perhaps from me I tried …, I could have perhaps gotten a little bit better, I could have got a bit more (PWA4)"

The variability in the opinions of participants on the massed dose of ILAT shows that this intensity of ILAT was not acceptable to all participants.

Interview data showed facilitators differed in their opinions about how much of an ILAT course would be comfortable to deliver. Some assistants enjoyed the challenge of taking on the role for the full 10 days and reported the benefit of this way of working would provide continuity and role satisfaction as the participant progress would be evident.

"Part of me thinks doing for the 2 weeks solid would be good they get used to you, you get used to them, you consistently know what's going on day to day. So you kind of build up the rapport with them but also you for them its consistent if it's one person the whole way through which I think is quite nice (F2)."

Conversely, other facilitators reported finding delivering ILAT courses very tiring and felt incapable of completing a full 10 day course. Volunteers felt that 2-3 days per week therefore 4-6 days in total was an appropriate amount to facilitate during a single ILAT course.

"*I couldn't do it all the whole time it was exhausting, mentally exhausting… it's just quite intense, there is so much concentration required. It really is quite full on when you're encouraging people and marking it you've got to be totally on it. Its full on (F3)"*

Whilst having less facilitators improved the continuity of ILAT delivery (see section 6.4.4.1 Programme management) the burden of delivering a full course was considered too great by some facilitators. This issues of balancing continuity with the burden of facilitating ILAT forms an important feasibility issue for ILAT facilitated by assistants/volunteers. Assistants found facilitating more days of ILAT less burdensome than volunteers therefore one consistent assistant could facilitate the course providing the continuity of care with the support of several volunteers to reduce the burden for the volunteers.

6.4.5.3 Treatment fidelity or optimisation

Interview data revealed facilitators felt capable of managing group dynamics and cohesion but found this element both challenging and interesting noting it took time for participants to become familiar with each other and that managing the anxiety of participants was an essential part of the facilitator role. This theme was further expanded by field notes and observations that found facilitators struggled with managing communication breakdown and providing clarifying questions particularly in

courses with participants with moderate to severe aphasia. This finding was further confirmed by fidelity assessment that revealed reduced completeness of DIL in ILAT course two which had participants that had moderate to severe aphasia (see 6.3.2 Completeness of Daily Intervention Log).

Assistants reported feeling responsible for supporting volunteers to improve the delivery of ILAT particularly around giving prompts and encouraging participants to work at the upper edge of their communication abilities. Assistants expressed some frustration at volunteers being more lenient on participants, risking treatment fidelity by not encouraging participants to work at the upper edge of their ability. However, assistants felt confident to give feedback to volunteers to maintain treatment fidelity (see section 6.4.3.1 Manual and training for details and interview data).

Interview data also exposed some boredom for participants with the game play

"…I think that would have kept the interest for me. I think to do a little bit more to it, another type of question … if you could (PWA8)"

"yeah that, asking for those cards it got a bit boring (PWA6)"

Conversely, other participants reported enjoying the language action games

"He got bored because it was the same pictures over and over again but I didn't I didn't mind, cause I cause all the cards I got I didn't have them at all, I got this one, I got this one ah but I might get five new ones… I got and I thought I can talk about this … but a new card I have something to say about that one (PWA9)"

Intervention coherence, a theme from the TFA(v2), was understood by participants as they discussed elements of the key components of ILAT including: group:

"Yes, yes, but it's not, its um… it's not um… it would having all, it had to be all that sort of person. I think everyone else got it with more getting more from other people (So you got more out of it in a group rather than doing it just with a therapist?) Definitely yes, certainly (PWA4)";

LAG's:

"Yes, we had sort of like err games really. That sort of thing (PWA7)";

shaping:

"We had to encourage each other to say what you … got to do (PWA3)";

tailoring:

"the planning bit I would have been happier with a bit more of the planning but that's because I wanted it go with the job I'm looking at (PWA8)"

and, focusing:

"I don't (know) whether it could be done, there was planning and request if there was something else maybe something else that could be done that was a little bit further than planning another level to add to it? (PWA8)"

Participants recognised the limitations of ILAT in the short two week duration

"… its only 2 weeks you can only do a certain amount in two weeks (PWA6)"

and also in participating in a group therapy:

"The people that were in the … (group) that was why it was done because they were all different… (Maybe you would like to have people matched more closely but there is some benefit from having people different from yourself in the group) Yes I believe so (participant)", "*…But there again you have to be everyone there for your everyone (gesturing around the table)… hold on… (Are you thinking it needs to suit everyone in the group?) Yes you have to go to the slowest… not the highest (PWA4)."*

Facilitators also discussed intervention coherence stating that training helped them to understand the intervention but experience was necessary to truly understand ILAT.

"Like at the time, I was like ah okay, I understand it, I get it, but until you actually do it, you don't know" Intervention coherence (F5)

6.4.5.4 Dose received

Attendance data revealed all participants attended all delivered ILAT sessions in ILAT courses one and two. In ILAT course three one participant missed three sessions and another participant missed one session. Finally, in ILAT course four one participant missed one session. One participant in course one did not receive any ILAT sessions as the participants was unavailable for the allocated course. Two participants in course four withdrew prior to receiving any ILAT sessions. One due to anxiety about coming to the hospital and one participant with severe aphasia who was unable to describe the reason for withdrawal due to the severity of the aphasia. Resulting in three out of 16 participants a total of 19% did not receive ILAT.

The interview data confirmed the attendance data in that participants felt they were capable and willing to complete a course of ILAT after they had received the intervention.

"I said to her (another participant) we'll do it, you and me we'll do it, do it together, do it all (PWA7)"

"I coped with it (PWA5)"

Whether the dose was acceptable to participants varied some participants wanted a little less and some wanted more (see section 6.4.5.2 Dose delivered per protocol). Missed sessions further compounded the reduced dose of ILAT actually received which was an important feasibility issue for the massed and intensive delivery of ILAT.

6.4.6 Intermediate outcomes

6.4.6.1 Decrease in severity of aphasia

The quantitative outcomes for the Therapy Outcome Measure (TOM) activity and impairment are reported in detail in Table 39. Overall in terms of the treatment effect the results are equivocal. The study gives no evidence of effect in favour of ILAT. Discordant interview data coded to the theme perceived effectiveness (TFAv2) revealed, some participants reported a perceived improvement;

"All of a sudden, you're talking about things you've never talked about before (PWA2),"

"I think probably I'm using it more I'm speaking…yeah, even more if I dare say that but I'm not stopping as many times…a a bit, mainly speaking they're coming out more regularly (PWA9)"

Some carers felt there was an improvement in expressive language for example

"...but when you're actually talking between yourselves she may not get all the words right she is much more fluent (carer PWA3),"

"...when he's on his own and his quiet just him and me he comes out with really long words, so yes he's improved (carer for PWA5)".

Interestingly, the opinions of carers and participants often diverged. On some occasions the participant felt their expressive language had improved and the carer did not feel the same and on other occasions the participant with aphasia did not perceive the difference however, the carer reported an improvement. Other participants did not fell their communication had improved.

"I don't really know how you alter much with it really do you? (PWA3)"

6.4.6.2 Improved communication confidence

Again, there was no indication of impact on communication confidence on the mean score within the quantitative data recorded on the COAST -5.75(-13.76 to 2.26). On individual analysis of the question regarding confidence within the COAST Figure 21 shows a slight shift to higher categories or improved confidence from baseline to four month outcome for those who received ILAT. Participants were divided on their perception of communication confidence following the ILAT course. Some participants felt it helped

"I definitely felt more relaxed talking to everybody (PWA8)"

"I go in a shop, and talk and I'm still not 100% sure, ask for something… I didn't use to… Yeah I would've walked in looked round and went (PWA6)"

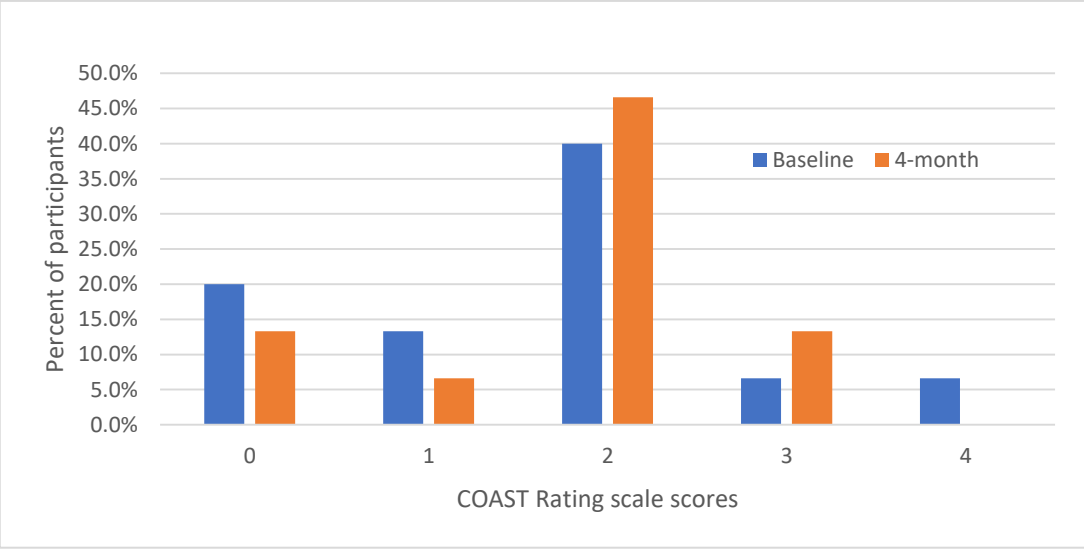
whereas, other participants continued to report reduced communication confidence;

"No, no again it's have a look a little bit, just sus it out a little bit, even more so now (PAW4)"

"Not now. (Not now, you're not very confident now … did you used to be more confident?) Yea (PWA1)"

Therefore, the interview data confirmed the quantitative result from the COAST reflecting that some participants felt improved confidence where others did not.

Figure 21 Baseline and 4-month outcome scores for confidence question of the COAST for ILAT arm



6.4.6.3 Improved naming, auditory comprehension and spontaneous speech

Neither the naming subtest of the CAT (-0.53 95% CI -5.54 to 4.49) nor the picture description subtest (-1.56 95% CI -8.58 to 5.47) of the CAT showed any treatment effect however some discordance was found as participants reported some improvement in naming,

"well, well I think I can do things out with the speech that I didn't do before (PWA7)."

Where others reported no change in naming ability or spontaneous speech.

"I think, no it's just about no much I think (no change in finding the words?) (PWA3)"

6.4.7 Longer-term Outcomes – Generalisation to untreated words and communicative contexts

Likewise, some participants felt that the ILAT course had generalised to communicating more effectively in everyday conversations.

"I go in a shop, and talk and I'm still not 100% sure.. ask for something, but it's the case of have you got this one (PWA6), "

"(so are you finding that that's better now in your everyday life since the therapy) well nobody's said, well nobody's reminded me that I haven't … can't think of it at the minute cos my husband, he's one who will say a word an and he'll ya know if I haven't said something, he'll think he's got to find me a word (help to find it… so that hasn't happened since (the ILAT course) not so much no (PWA9)."

"yes just slowed it down…if he couldn't say it was trying to think how can I say it how can I say it. He seemed to slow himself down so he could say each word individually so he could say more words but slower (carer of PWA4)"

Conversely, this perception was not confirmed in the quantitative outcomes which do not show any generalisation to untreated words on the CAT, or to communicative contexts on the TOMs.

The triangulation of the data revealed a mixed picture of feasibility and acceptability of assistant/volunteer facilitated ILAT. It was feasible to form ILAT courses, participants and facilitators were motivated and willing to facilitate/complete courses of ILAT, treatment materials were prepared and tailored, participants were able to travel to receive treatment and care needs were met whilst participants attended the courses. Participants reported assistant/volunteer facilitated ILAT to be acceptable and mostly enjoyable. Facilitators reported ILAT was acceptable however, some facilitators felt there was a limit to the amount of ILAT they would be able to facilitate. Conversely, dose delivered and received failed to reach the desired level with only two thirds of ILAT being delivered and less being received. Some participants also reported the massed does was not

acceptable as it was too tiring. Issues were identified in the manual and training for facilitators that resulted in threats to treatment fidelity particularly focused on DIL completion, intervention coherence and supporting participants to complete ILAT LAGs through the use of prompts and feedback. Some additional issues were identified in the completion of the DIL that threatened the ability of the research SLT to provide adequate case management and progress participants through the ILAT courses. The next section examined the issues identified through the triangulation of the data and solutions were proposed and trialled where possible.

6.5 Approaches taken to modify ILAT to improve feasibility and fidelity of delivery, and acceptability to facilitators and patients

Identified problems and solutions have been tabulated in Table 48. Problems have been divided into eight categories which relate to the inputs, activities and outcomes within the logic model (see Figure 9 pg. 88). Five of the problems also relate to the essential components of the treatment theory (Figure 7 pg 62). The remaining seven problems relate to resources and logistical activities required to carry out ILAT using trained assistants/volunteers on the NHS.

Table 48 Changes to intervention (ILAT)

Change Number	Problem	Solutions
1	Misunderstanding of ILAT components	
	Clarification questions Facilitators had difficulty generating clarification questions	Further training was provided, example clarification questions were added to the manual (changes were made after ILAT course 1 and delivered in remaining three courses)
	Prompts and feedback Facilitators were confused about the definition of prompts (semantic, phonemic	Further training was delivered, manual terminology was updates (clue, first sound)(changes made after ILAT course 2 for delivery in ILAT course 3 and 4)
	Appropriateness rating Appropriateness ratings were inconsistent between facilitators	Further training provided including on line scoring of DIL with peers whilst completing LAG's, scripts with scored DIL added to manual (changes made after ILAT course 2 and delivered in ILAT course 3 and 4)
	Rules Inflexible use of carrier phrase	Further training required (this item was identified in ILAT course 4 interviews and therefore not addressed as further courses were not being completed)
2	Clinical Data integrity	
	Facilitators recorded other participants scores on the wrong DIL	A box was added to the DIL so that facilitators could clearly mark each page with the initials of the participant (change made after ILAT course 2 and delivered in course 3 and 4)
	Facilitators preferred the tick box DIL	The preferred DIL was used in training and completion of the three remaining ILAT courses (change made after ILAT course 1 and delivered in remaining ILAT courses)
	Facilitators struggled to complete the DIL in a group of four particularly with moderate-severe patients	The next moderate-severe ILAT course was trialled with a maximum of three participants (changes made before ILAT course 4 and delivered in course 4)
3	Treatment room	
	Difficult to secure space for all 10 days ILAT course 1 had to move between two rooms on the same corridor	Subsequent rooms were booked further in advance and space was secured in the same room for all 10 sessions of each group (changes made after ILAT course 1 and delivered in remaining courses)
	Treatment room was too small in ILAT course 1	For ILAT course three and four larger rooms were located (change made after ILAT course 2 and delivered in ILAT course 3 and 4)
	Facilities (kitchen and toilet) were inaccessible without a staff member	ILAT course four was located on the stroke unit with ready access to toilet and kitchen facilities in close proximity and freely accessed by participants (change was made before ILAT course 4 and delivered in course 4)

4	Treatment materials	
	Required more cards to maintain interest	Facilitators made more treatment cards based on participant interest and frequent word cards for severe participants (changes made after ILAT course 1 for mild-moderate severity of aphasia and ILAT course 2 for moderate-severe aphasia)#7
	Some boredom identified in repetitive nature of request/planning format	Added the addition of a competition element for ILAT course 3 (mild-moderate aphasia change made after ILAT course 2)
5	Facilitator recruitment	
	Delayed commencement of ILAT course two due to facilitator unavailability	For ILAT course three and four one assistant facilitator was released from regular duties to complete the two courses (change made after ILAT course 2
	Unable to recruit volunteers Contacts through the NHS trust volunteering lead did not produce any interested volunteers	Therefore a personal approach was tried and resulted in two volunteers being recruited (change made after ILAT course 2)
6	Continuity of care and hand over between facilitators	
	Facilitators did not overlap between session – handover was recorded on the DIL Facilitators felt uncertainty around participant performance and applying the prompting and rule components outlined on the DIL. Also participant confidence was affected by new facilitators coming to each session.	ILAT course three and four had a consistent facilitator so handover could be coordinated by the facilitator who had attended the previous day and be a consistent support for participants (change made after ILAT course 1)
	General wellbeing was affecting participation and no way to handover details was available to facilitators	A section was added to write information about general wellbeing on the DIL and a consistent facilitator was released to complete ILAT (change made after ILAT course 1)
7	Transport	
	Two participants had transport issues	We sought out volunteer drivers, participants after they had met agreed to provide transport as required (change made after ILAT course 1)
8	Attendance	
	Missed sessions - 2 participants attended 90% of ILAT sessions and 1 participant attended 70% of sessions.	No solution to this issue was identified

Change number one and two provide solutions for problems that threatened the treatment fidelity of ILAT and the integrity of the clinical data collection.

A list of sample clarification questions was added to the manual, and simplification of the terminology for prompting was completed (phonemic and semantic became first sound and clue) to ensure fidelity of the "prompts and feedback" aspect of the intervention, while training was reconfigured to support facilitators use of prompts and feedback through training experience using both transcripts with scored DILs and playing LAG's amongst facilitators to simulate on-line scoring of the DIL. Training was also reconfigured to clarify the appropriateness rating of participants LAG turns. Additional scripts of participant LAG turns were provided with completed DILs to support integrity of the clinical data collection and supervision process. Further description of the carrier phrase component was added to the manual to clarify the acceptance of any and all versions of the carrier phrase and example carrier phrases were added to the manual.

ILAT course two contained four participants in total, two of which had severe aphasia. Therefore, facilitators were required to provide more support through prompting and feedback to mediate a higher rate of communication breakdown. The burden on facilitators was further compounded by participants being less able to independently ask clarifying questions which meant facilitators were required to mediate clarification questions whilst still completing the DIL. Fortunately, a chance to trial reducing the number of participants arose in ILAT course four which was the next course treating participants with moderate to severe aphasia. Two participants withdrew from this course prior to commencement which allowed the course to run with two participants. Fidelity assessment revealed that completeness of components on the DIL improved between ILAT course two and four with all components being recorded more completely (see Table 43). Confirming facilitating a course with two participants was more acceptable.

It was observed that facilitators were writing the initials of the participant at the top of each page and interviews revealed that it was easy to incorrectly mark the DIL with the wrong participants LAG turn as assistants were marking up to four records in turn. Therefore a box was added to ensure all participant initials were on each page after ILAT course 2. On observation and in supervision discussions in ILAT courses 3 and 4 only one instance was recorded of participant LAG turns being recorded on the incorrect DIL. After it was identified that facilitators were using only the tick box version of the DIL all further training and the remaining three ILAT courses used only this DIL.

Change number three provided solutions for problems associated with treatment rooms. Interview data and observation resulted in ensuring one room was available for the ten sessions of ILAT

courses two through four. As participants and facilitators are spending a large amount of time each day in this one room a room that allowed easy movement and was comfortably large enough was sourced and also that had ready access to kitchen and toilet facilities for ILAT course four was sourced. Interview data for participants who attended ILAT course four did not contain any themes about facilities or dissatisfaction with accommodation. However, quantitative data revealed that improved access to kitchen and toilet facilities did not result in an increase in the amount of minutes ILAT was delivered each day (see Table 42).

Change number four provides solutions for reports of boredom caused by limited treatment materials. Additional cards were produced throughout ILAT courses one through three. These materials were tailored as far as possible to ensure participant satisfaction. Additional materials including introducing more game types (including the element of competition) was added during course one, two and three to maintain interest. In the fourth and final ILAT group participants and facilitators did not make any further comment about limited materials.

Supervision discussion revealed participants' interest and motivation were affected by repetition causing boredom in ILAT course three containing participants with mild-moderate aphasia. So, the usual game play of asking each player in turn was modified to add an element of memory and competition. Participants asked another participant for a request or planning LAG but if unsuccessful with the match on the first attempt then the turn ended. Somewhat like the game 'Old Maid' or 'Go Fish'. This game play required participants to listen more carefully and remember which participant had a desired card to make successful matches and win the game. This game play was introduced in ILAT course three and interview data revealed that participants found it interesting and would like to play in this format more

"but then they said memory, memory ask for a picture, ask somebody, you had to ask someone and remember who had it. (A bit more of a competition than asking each person?) Yeah if we done a bit more on that side (PWA8)."

Change number five dealt with difficulties in recruiting facilitators for delivering ILAT courses. ILAT course one and two were completed with a rota of up to six assistants. Releasing this number of assistants was difficult for the NHS trust. Therefore, one assistant was identified and released to lead ILAT course three and four which allowed for improved continuity of care and provided a much more stable delivery of ILAT.

Change number six addressed issues compromising continuity of care. A further section was added to the DIL to handover additional details of participant general well-being and performance during ILAT to smooth the transition between facilitators who had not attended the previous days sessions.

For ILAT courses three and four one assistant was released to lead the courses rather than relying on a rota of assistants to fill the course. This allowed for the continuity to be provided by this consistent facilitator who took on the role of handing over information about performance, progress, new rules and targets and general wellbeing of participants.

Change number seven provided solutions for issues that arose with transport to the treatment centre. Participants were able to access use of some public transport and once the participants had met car sharing was also arranged.

Participants not attending all sessions of ILAT was unavoidable and no solution was found to prevent this from happening as the reasons for non-attendance were prior appointments and illness. However, this represents the reality of treating people with aphasia in the NHS.

Two issues remained after the iterative process of refining assistant/volunteer facilitated ILAT was completed across the four courses delivered during the pilot RCT. The full dose of the intervention was not delivered with two issues identified that impacted this outcome, firstly that there was not enough time in the schedule to complete comfort breaks and secondly some participants did not attend all sessions.

6.6 Conclusion

There was no suggestion of treatment effect in the clinical data collected. Several factors may have contributed to this; participants did not receive the full 30 hours of intended dose, outcomes may not be the most appropriate or sensitive for measuring the treatment effects, the treatment theory may not be correct and, statistically the small number of participants does not allow for effectiveness to be assessed. The outcome assessments did not identify that ILAT had triggered the desired mechanism of change. These issues are further explored in Chapter seven. Other identified barriers to success of ILAT were address through refinement of training and procedures between courses.

Participants found it acceptable for assistants/volunteers to facilitate ILAT. Assistants/volunteers found the role of facilitating ILAT courses acceptable after refinement of the treatment protocol and logic model between courses. Some participants described changes in confidence and communicative effectiveness that were not confirmed by the clinical outcome measures. However, acceptability regarding dose, intensity and duration of treatment varied between participants and assistants/volunteers.

Feasibility improved across the four ILAT courses. Fidelity assessment revealed issues that threatened the faithful delivery of ILAT and the integrity of the clinical data collected. However, the iterative process of evaluation and development of the manual, training sessions and supervision improved both the adherence to the treatment protocol and integrity of the clinical data across the four courses of ILAT.

Chapter Seven: Discussion

This chapter summarises how the thesis objectives were achieved, describes and interprets the principal findings of the ILAT Pilot trial, qualitative study and the triangulated results, comparing these findings to other studies examining ILAT. The strengths and limitations of the work are considered and the feasibility of conducting a definitive trial evaluating assistant/volunteer facilitated ILAT and questions for future research are discussed

7.1 Summary of findings

The overall aim of this thesis was to identify, develop and evaluate an intervention that could be delivered intensively and efficiently within the NHS to improve the communication of people with aphasia. This aim was achieved through the following five objectives:

1) Identify an intervention for aphasia that targets conversation, can be intensively and efficiently delivered, and has the best evidence (chapter two)

Through reviewing systematic reviews of interventions for aphasia, Intensive Language Action Therapy (ILAT) was identified as an intervention that had been delivered intensively, efficiently both in a group and facilitated by laypersons, and had the best available evidence. The quality of the evidence for ILAT was rated low through GRADE. Therefore, further research was required to evaluate ILAT in a randomized control trial design. ILAT also needed to be compared to usual care within the context of the NHS to evaluate how it could be implemented in this context.

2) Review how the mechanism of action for an intervention that targets conversation has been described in the literature (chapter three)

Five essential categories of components of ILAT were identified that target the principles of experience-dependent learning that are believed to trigger the proposed mechanism of Hebbian learning these are: salience (component is language action embedding which is actioned through the use of card exchanges, Language Action Game's and the group context); intensity and repetition (component is massed practice which is actioned through the use of ILAT delivered for

30 hours over ten days); specificity (components are prompts and feedback which are actioned through using clarification questions and reinforcement contingencies); use-it-and-improve-it (components are shaping and tailoring which are actioned through the use of reinforcement contingencies and stimulus materials); and, use-it-or-lose-it (component is constraint/focusing which is actioned through the use of barriers, reinforcement contingencies and stimulus cards).

3) Describe how to operationalise an intervention that targets conversation to be intensively and efficiently delivered on the NHS (chapter three part two and chapter four)

The development of a programme theory and logic model allowed ILAT to be operationalised for delivery on the NHS facilitated by assistants/volunteers through the development of a treatment manual, a training package, a daily intervention log and distant supervision provided by a SLT. The iterative evaluation was used to refine these procedures for the delivery of ILAT facilitated by assistants/volunteers.

4) Determine if it is feasible to evaluate an intervention that targets conversation and can be intensively and efficiently delivered in a randomised control trial (chapter five)

The primary purpose of the pilot trial was to determine feasibility of conducting an RCT. Criteria demonstrating feasibility were set prior to the pilot study and were achieved as follows:

- to recruit at least one participant per month: this study achieved a recruitment rate of 1.87 participants per month;
    - completion rates for the primary outcome of at least 80%: this trial recorded a primary outcome completion rate of 82%;
    - positive reports from stakeholders about acceptability of all trial procedures: participants and assistant/volunteers reported trial procedures including outcome assessment were acceptable;
    - recruitment and retention of assistants and volunteers: enough assistants/volunteers were recruited to complete four courses of ILAT and six out the ten assistants/volunteers remained in the trial for at least two courses of ILAT.

5) Determine if it is feasible and acceptable to deliver an intervention that targets conversation and can be intensively and efficiently delivered in the NHS (chapter six)

The results revealed a mixed picture of feasibility and acceptability of assistant/volunteer facilitated ILAT. Participants found it acceptable for assistants/volunteers to facilitate ILAT.

Assistants/volunteers found the role of facilitating ILAT courses acceptable after refinement of the treatment protocol and logic model between courses. Fidelity assessment showed that, following the iterative development of the training and ILAT manual, the daily intervention log completion and daily supervision resulted in ILAT that was delivered with high fidelity for the components; group, card exchange, Language Action Game, prompting, rules, materials and barrier use. Low fidelity to the delivery of treatment dose (only around two thirds of the intended dose was delivered) and variable fidelity to extending people with severe aphasia to their best communicative ability remained after the iterative development process. Although not powered to detect an effect, there was no evidence of a treatment effect in the clinical data collected for this small sample, although some participants and their carers described changes in confidence and communicative effectiveness during qualitative interviews. ILAT was compared to usual care with conversational ability rated using the Therapy Outcome Measure's (TOMs) Impairment scale; an adjusted for baseline mean difference of -0.28(95% CI -0.79-0.23) was found and the TOM's Activity rating; an adjusted for baseline mean difference of -0.24(95% CI -0.54- 0.59) was found. Naming ability was assessed using the Comprehensive Aphasia Test (CAT) object naming subtest; an adjusted for baseline mean difference of -0.53(95% CI -5.54-4.49) was found. The CAT picture description subtest was used to assess discourse; an adjusted for baseline mean difference of -1.56(95% CI -8.58-5.47) was found. Overall, the usual care arm participants performed slightly better across all clinical outcomes. The absence of a treatment effect could well be down to a Type II error, reflecting the play of chance in a small sample. Notwithstanding the sample size, it was hoped (and some funders would have hoped) to have seen an efficacy signal as an indication of whether the intervention had potential, which was not seen in this pilot trial.

7.2 Strengths and Limitations

A discussion of strengths and weaknesses of the studies in the thesis and existing literature on ILAT help to provide context for the findings of the evaluation.

7.2.1 Strengths of the programme theory

The Medical Research Council recommend that complex interventions are designed with theoretical underpinning, described, defined, developed then evaluated including examination of the contextual factors that impact the outcomes. A strength of this study is that it followed these recommendations through the systematic identification of how ILAT (review of systematic reviews) theoretical underpinning, key components and intended outcomes have been

described (ILAT treatment diagram see Figure 6 pg. 62) which then provided enough information about implementation needs to guide a comprehensive evaluation, guiding how data needed to be collected, analysed and reported.

A strength of this programme theory was that it attempted to describe the key components and identify the underlying mechanism of action of ILAT in order to support delivery on the NHS. There was inconsistency in how CIAT/ILAT were delivered in the literature with no clear consensus of which components were essential to the delivery of ILAT and variability in the manner in which the components were delivered. Beyond what components of ILAT were delivered, how these components were delivered varied between trials. The inconsistency in delivery makes it difficult to determine how ILAT should be implemented in practice. Therefore, the development of the proposed treatment theory in this study provides a clear description of what ILAT is and how it can be delivered.

7.2.2. Strengths and limitations of the logic model development process

The logic model was designed to describe the context for delivering ILAT and attempted to present the resources and activities required to deliver assistants/volunteer facilitated ILAT in the NHS. Evaluation of processes is grounded in system theory which contains three elements: 1)boundary definition, which is the identification of issues that should be included and excluded; 2) identify and record dynamic interrelationships and 3) encompass multiple perspectives from all stakeholders (232). In this study the logic model was not developed with stakeholder input, instead it was formulated by the research SLT. However, logic model constructs were discussed in interviews with stakeholders, both participants and assistants/volunteers. In this process no new inputs or activities were identified and no new interactions between the inputs and activities were identified. This resulted in validation of the logic model.

Critics of logic models state that it is possible to miss important interdependent variables as the single causal strand of the logic model is too rigid to display interactions and too simplistic to describe the context (232). A weakness of this logic model was that some of the processes within the model were displayed in single boxes where a whole process model could be dedicated to the single element. For example the delivery of ILAT was displayed in one box on the model where an entire manual, training and experiential learning was required to deliver ILAT. This was also the case for case management and programme management. As a result, this was a

simplified heuristic representing the more complex process of delivering ILAT that allowed the major consideration of inputs, activities and outcomes to be described, piloted and evaluated.
Of those processes that were more complex the programme management had some limitations which impacted the delivery of ILAT. The training package for therapy assistants/volunteers did not support high fidelity to the delivery of ILAT particularly in extending participants with aphasia to work at the upper limit of their communicative ability. Therefore, resulting in participants, particularly those with severe aphasia, not receiving the optimum treatment and may in part explain the lack signal in the data.

7.2.3 Selection of ILAT

A strength of this study was the fact that a systematic review process with clear inclusion criteria was used to identify ILAT as an intervention with best available evidence that could be delivered intensively and efficiently and attempted to improve conversation through targeting spoken language. However, Pulvermuller, the originator of ILAT, is heavily involved in the production of research into CIAT/ILAT. Of the 30 research studies included in the review presented in chapter three, 11 (36%) listed the originator, Pulvermuller as an author of these. Ten of the 11 studies (91%) reported statistically significant results on at least one outcome. Of the remaining 19 independent studies six reported no statistically significant results with only small or no gains though two of these studies reported clinically meaningful gains. The remaining 13 (68%) studies report statistically significant result on one or more of the outcomes assessed. Therefore, the originators work represents a high proportion of the ILAT literature with more positive results than independent studies. The fact that those studies where Pulvermuller was involved are producing better results may represent an intervention delivery agent bias; meaning that the level expertise within teams delivering ILAT under the supervision of the originator are different to those that have delivered ILAT independently (233). These factors might mean that ILAT may not be as effective as it first appeared in the literature. This may also go some way to explain the difference in the results found in this study as compared to the results found in the literature.

7.2.4 Strengths and limitations of the pragmatic pilot trial design

The pragmatic trial design was a strength in that it allowed the research SLT to examine ILAT delivered in as close to possible the everyday clinical context in which it would be delivered within the NHS rather than controlling the delivery of ILAT in a more explanatory approach (186). The pragmatic design allowed the tailoring of ILAT to meet the communication needs of the participants through the tailoring of materials and vocabulary supporting the principles of

experience-dependent learning. This flexibility in tailoring ILAT is also how SLTs would deliver ILAT in practice but means that ILAT was not delivered in a consistent manner.

A limitation of this study is that the individual components of ILAT; language action embedding, intensity/massed practice, constraint/focusing, shaping and tailoring have not yet been evaluated independently to determine which of the components contribute to the anticipated treatment effect. In addition, Hebbian learning is hypothesized to be the mechanism of action, but there is not yet any evidence to confirm that the components of ILAT do indeed work through this mechanism of action. To this end, the COMPARE study (Constraint-induced or multi-modal personalized aphasia rehabilitation (COMPARE): A randomized controlled trial for stroke-related chronic aphasia) by Rose et al. (2019) is in progress which is evaluating ILAT compared to an unconstrained intervention (M-MAT) to determine the impact of constraint or focusing on speech to achieve outcomes for aphasia. Also, Stahl et al. (2018) compared different intensities of ILAT to determine the effect of massed practice on the communication outcomes following ILAT.

Given the lack of evidence for the components and mechanism of action of ILAT, it could be argued that conducting a pragmatic trial was premature. However, the focus of this study was on the efficient delivery of ILAT facilitated by assistants/volunteers as this would allow ILAT to be delivered within the context of the resource limited NHS. Furthermore, if further explanatory research is produced, identifying and refining the most important and effective components of ILAT, any potential improvements identified to ILAT could be incorporated into the training and supervision designed in this study therefore, providing the vehicle for delivering ILAT in the NHS.

The pragmatic nature of the trial was limited in this study due to the heavy involvement of the research SLT in the training and supervision of assistants/volunteers which would not happen in clinical practice. This iterative process of refining ILAT procedures and training was essential to optimise the treatment protocol and training package prior to delivering a definitive trial. Having said that, evaluating performance and providing support and feedback in this way to assistants/volunteers who were learning how to facilitate ILAT would be the role of a SLT in usual practice and it is not unusual for assistants to follow a competencies framework to establish proficiency that is not dissimilar to what was completed in the pilot trial. Therefore, the issues identified throughout the pilot would likely be issues encountered when attempting to deliver ILAT in the context of usual care in the NHS. Research indicates that assessment of

fidelity and feedback improves adherence and can validate performance and improve motivation for practitioners delivering interventions (234).

In pragmatic trials fidelity is typically measured rather than ensured however, as this study was about the feasibility of the methods and the intention was to refine the intervention, processes were improved to try and improve fidelity across subsequent ILAT courses.

7.2.5 Strengths and limitations of outcome measures

Conversation in everyday life is the targeted longer-term outcome of ILAT however measuring the impact of ILAT on conversation is difficult. A recent core outcome set was developed for aphasia research and no consensus was reached on an appropriate outcome measure for conversation (200). Only one study in the literature evaluating ILAT reported using a conversational sample to evaluate discourse. The remaining studies utilised story re-telling or picture description which are not assessing conversation but instead discourse or connected and spontaneous speech (235) which might explain why the results of some ILAT studies are positive due to measuring different constructs.

A pragmatic approach to outcome measure selection for this pilot was taken using the literature to identify measures that could be matched to the goals of ILAT. The Therapy Outcome Assessment activity and impairment scales were selected as the primary outcome for this pilot study. Other studies that had been conducted with people with aphasia and had the same goal of assessing whether the evaluated intervention impacted the conversational competence of participants, had used the TOMs (211,236,237).

Strengths of the TOMs include: good psychometric properties with good inter and intra rater reliability and validity particularly where training was provided (202) and the activity scale has been standardised for use in research (237). A strength of applying the TOMs in this pilot study was that Training was given to the rater to ensure correct use of the TOMs in this research. SLTs are also familiar with using TOMs in everyday practice and this was the case for the SLT who completed the ratings in this pilot trial. A weakness was that there was only one rater so inter-rater reliability was not established. Weaknesses include the fact that some concerns about the TOMs rating have been raised as it may not be sensitive enough to identify small changes (238) and TOMs is also very subjective, relying on an SLT to judge whether conversational competence has changed. This lack of sensitivity in the TOMs may have contributed to the equivocal results

found in the this pilot particularly in light of the positive outcomes reported by some participants and their carers in the qualitative interviews. Recent recommendations for outcome measures in aphasia research failed to reach a consensus about the measurement of functional communication (200) and given the lack of signal in this trial and its reported lack of sensitivity a more appropriate and sensitive outcome measure may need to be identified before a definitive trial is conducted.

The intermediate outcomes of ILAT were identified as an increase in communicative confidence, improved naming of objects, and improved spontaneous speech. These outcomes are discrete skills that comprise communication and are proposed to support the ability to have conversations in everyday life. To examine the potential effects of ILAT in more detail outcome measures were selected to assess these communicative skills.

In this pilot study the Comprehensive Aphasia Test (CAT) naming objects subtest was selected to assess the naming ability of participants. The strengths of the CAT are that it has good inter-rater and intra-rater reliability and test-retest validity and was normed on a UK population of people with aphasia (205). SLTs in the UK are familiar with the CAT and the SLTs who completed the outcome assessments in this pilot trial were familiar with the CAT from use in everyday practice and also in other research conducted within the NHS Trust. Training was given to the outcome measure SLTs to ensure consistent administration and scoring.

The CAT picture description subtest was chosen to examine the spontaneous speech of participants. Again the reported inter and intra-rater reliability and test-retest validity are good and it is quick to administer and score. Training was given to support outcome measure therapists to administer and score the picture description consistently.

However, the recent recommendations for outcome measures assessment for naming and spontaneous speech were to use the Western Aphasia Battery subtest picture description (200) and had this consensus been available at the time of commencing this pilot trial the Western Aphasia would have been the outcome measure used in this research. Furthermore, several of the studies finding positive outcomes following ILAT have used entire language batteries such as the Western Aphasia Battery – Aphasia Quotient. Whilst this battery presents more of a burden to participants and researchers it would be interesting to see if measuring the impact of ILAT

across this battery would provide better insight into changes made following treatment with ILAT.

Participant and carer perceptions of communication competence in everyday life were assessed using the Communication Outcomes After Stroke (COAST) scale and Carer COAST scale. Again the reported inter and intra-rater reliability and test-retest validity are good and it is quick to administer and score. Training was given to support outcome measure therapists to administer the scale. However, the recent consensus for the assessment of quality of life were to use the Stroke and Aphasia Quality of Life Scale (SAQoL-39(200)). In comparing the COAST and SAQoL-39 there are similar questions that are explored in assessing communication and the SAQoL-39 includes more questions about activities of daily living that were assessed through the EQ5D in the trial. The SAQoL-39 does not ask questions about communication confidence or the participants perception of changes in communication since suffering a stroke. It is not clear whether the SAQoL-39 would measure changes produced by treatment using ILAT beyond those measured by the COAST.

7.2.6 Strengths and limitations of the qualitative study

A Strength of the qualitative study were that all stakeholders were interviewed and that these interviews were conducted in a way that allow issues identified to be addressed prior to next course of ILAT. In this way the fidelity of delivery to ILAT was improved between each ILAT course. A further strength of the qualitative research was that all people with aphasia, no matter severity were included. Using a confirmatory approach of questioning allowed the opinions of those with severe aphasia to be included. The limitations of the qualitative study were that no purposive sampling was completed and a limited number of usual care interviews were conducted that may not have resulted in the full understanding of the opinions of the usual care participants to be collected.

7.3 Acceptability and feasibility of assistant/volunteer facilitated ILAT

This pilot assessed the feasibility and acceptability of using a distant supervision model that allowed assistants/volunteers to facilitate ILAT under the supervision of a SLT. The following discusses the acceptability and feasibility of this model of delivering ILAT within the NHS.

7.3.1 Acceptability of assistant/volunteer facilitated ILAT

It was acceptable to assistants/volunteers, participants and the research SLT to deliver ILAT facilitated by assistants/volunteers. Participants accepted assistants/volunteers in the role of facilitator and assistants and volunteers enjoyed and felt capable of completing the facilitator role.

There were some differing opinions about the acceptability of the ILAT course dose, intensity and the massed schedule from assistants/volunteers and participants. It may be more acceptable if the dose were two hours each day maintaining an hour for breaks, which would take the dose in line with more recent research that reported that delivering more than 20 hours did not result in further benefit to participants (77). There was a set schedule for the delivery of the three hours of intervention each day that was not altered during the pilot. The schedule dictated that participants completed an hour of ILAT took a 15-minute tea break completed another hour then took a half an hour lunch break then completed the final hour of ILAT. There was a 15-minute buffer at the beginning of each session to allow participants to arrive and settle prior to starting the first hour of ILAT. However, the maximum dose of ILAT that was delivered was 21 hours and 49 minutes. Whilst no clear issues were identified that were preventing the delivery of the intended 30-hour dose perhaps the schedule was too tightly constructed, not allowing enough time for breaks and language action game set up.

19% of participants allocated to ILAT (three out of 16) did not receive a course of ILAT which resulted in a total withdrawal rate from both treatment and usual care was 11% (three out of 28). Whilst 19% withdrawal does appear to be high and casts some doubt over the acceptability of ILAT, this figure is no higher than the withdrawal rate of other pilot studies of a similar aphasia population (239). The assumption for the sample size calculation was based on one such study which had a 15% withdrawal rate taken from both the treatment and control arms (201). Therefore, this pilot had a lower withdrawal rate of 11% compared with 15% for a trial of a similar aphasia population using similar outcome measures (239).

7.3.2 Feasibility of assistant/volunteer facilitated ILAT

In terms of recruitment and retention of assistants and volunteers it was feasible to recruit assistants to facilitate ILAT from the pool of therapy assistants across allied health disciplines. Most assistants facilitated several sessions across ILAT courses demonstrating it was feasible to deliver ILAT facilitated by assistants. Recruiting volunteers was much more difficult resulting in

only recruiting volunteers for ILAT courses three and four. The strategy of recruiting volunteers through a mail out to existing volunteers within the NHS trust was unsuccessful. Volunteers were only recruited through personal contacts. Research shows that personal contact as well as word of mouth are the most successful ways to recruit volunteers (240). Once the volunteers were recruited however, they did complete the two remaining ILAT courses demonstrating good retention.

7.3.2.1 Fidelity issues during delivery of assistant/volunteer facilitated ILAT

There were issues with assistant/volunteer fidelity to ILAT methods across all four courses of ILAT. Fidelity improved across repeated courses of ILAT as training and the treatment manual were iteratively improved and also as assistants/volunteers gained more experience of ILAT.

The prompting component of ILAT was more difficult to train assistants and volunteers to achieve than adhering to other components of ILAT such as rules or modelling language action turns. This component of ILAT is essential to the behaviour relevance of ILAT, extending participants to operate at the outer limit of their communicative ability and also supports the participants to learn how to provide more detailed responses or remediate communication breakdown.

The originator of ILAT asks facilitators to ask questions that clarify meaning. For example, asking where an item might be found or how it might be used or describing the item such as asking about shape or colour. These clarification questions can also be asked as forced choice questions such as 'is it big or small' or 'is it found inside or outside'. Learning to ask questions in this way was challenging for assistants/volunteers but was achieved through the SLT providing more example questions so that assistants/volunteers did not feel they were thinking of questions on the spot as well as more experience facilitating ILAT. Interestingly, across the sessions of ILAT participants began asking these clarifying questions of each other, particularly for those with mild to moderate aphasia. It appeared to be a natural consequence of ensuring that card matches were successful.

Issues remained after the final ILAT course with extending participants to work at the outer edge of their communicative competence due to volunteers providing answers rather than continuing with clarification questions. This lack of fidelity to the ILAT components may have reduced the likelihood of Hebbian learning. Instead singular activation of parts of the neural network may

have resulted which was then reinforced in a massed practice dose which has the potential to have a harmful effect on the neural networks. It would be interesting to consider whether this could have accounted for some of the reduction in outcome measure scores in the ILAT group as reduction was not seen in the usual care group. No similar finding was not reported in any other research studies of ILAT which may be a reporting bias but may also be unique to this delivery method of ILAT facilitated by assistants/volunteers. Also delivering the intended dose was not achieved throughout the four courses of ILAT. The intended dose of 30 hours of ILAT was never delivered. Research indicates that interventions delivered in a more distributed fashion, for example once a week had poorer rates of reaching the intended dose with the most successful dose delivered in a intervention that was delivered across five consecutive days (241). However, actual attendance was not the cause of poor dose delivery in this study. The majority of participants attended the course for the specified four hours however, three hours of ILAT were not delivered in this time. Whilst some issues were identified to do with facilities that were causing breaks to take too long, solutions to these issues resulted in only a small increase in dose. No additional reasons for the low dose were identified through the iterative evaluation process. It seems that there must be other unknown factors preventing the delivery of ILAT. It is possible that organising the language action games was taking away from intervention time. It is also possible the massed nature of ILAT was too intense for assistants/volunteers to deliver or for participants to receive and so motivating participants back to the intervention after breaks may have caused the issue. The reduced fidelity may in part account for the equivocal findings between usual care and the ILAT on the four-month outcome assessments.

Volunteers found delivering ILAT to be more challenging than assistants and often deferred to the assistant for support and reassurance of competence. It was feasible for volunteers to support assistants in facilitating ILAT but they were not competent or confident to facilitate ILAT without assistants.

7.4 Evaluation of efficiency of ILAT delivery

Delivering an intervention for aphasia that targeted spoken communication in conversation that could be delivered efficiently was the key goal of this study. In terms of the efficiency of the intervention the research SLT acted as the supervising SLT would if assistant/volunteer facilitated ILAT were being delivered in standard practice. It was never intended that the assistants/volunteer would be able or competent to independently deliver ILAT. SLT supervision would always be required to support the assistants/volunteers to select treatment goals,

Language Action Games rules and materials and to progress patients through the intervention to ensure patients were working to their full potential. By the final group the research SLT spent around two and half hours in supervision with assistants/volunteers which resulted in delivering 20 hours and 23 minutes of ILAT. Identifying the initial goals for patients would be a part of normal practice and would not represent an additional burden to SLTs in preparing patients to attend an ILAT course. The SLTs working in this way are then able to supervise patients receiving around 20 hours of therapy whilst still being able to continue treating and assessing other patients on the case load as the commitment to the course is approximately 15 minutes per day. Research tells us that SLTs are usually delivering 1-2 hours of therapy to each patient on the caseload per week (74). Working in this way with assistants/volunteers facilitating ILAT would allow SLTs to place up to four patients on their case load into an ILAT course thus, releasing up to 8 hours a week of treatment time to manage other patients in their care whilst those patients are receiving up to 20 hours of intervention in the ILAT course. In my own clinical experience patients also then requested a break from therapy for a few weeks following an intensive block of therapy. Patients could then cycle through periods of less intense therapy delivered one to one with an SLT or assistant as in usual care, periods of intensive, massed ILAT and rest periods. Restructuring services in this way could support SLTs to shorten waiting times as patients in the ILAT courses or rest periods would require limited or no input from the SLT whilst still being treated on the case load.

7.5 Pros and cons of delivering a definitive trial

Factors that would support delivery of a definitive trial: Recruitment was adequate and retention was acceptable with 82% of participants completing the primary outcome and six out of ten assistants/volunteers remaining in the trial for at least two ILAT courses. ILAT was delivered with high fidelity for the components; group, card exchange, Language Action Game, prompting, rules, materials and barrier use. Some participants and their carers reported positive changes in communication following receipt of an ILAT course. Participants reported assistants/volunteer facilitated ILAT was generally acceptable as did assistants/volunteers. Many aspects of the process of delivering ILAT facilitated by assistants/volunteers appeared feasible through-out the pilot trial. The progression criteria demonstrating feasibility of evaluating ILAT in an RCT were all met.

Factors to consider prior to delivering a definitive trial: Low fidelity to the delivery of treatment dose (only around two thirds of the intended dose was delivered) and variable fidelity to

extending people with severe aphasia to their best communicative ability remained after the iterative development process showing some important limitations to the feasibility of assistant/volunteer facilitated ILAT. Further development of the treatment manual and training need to be completed to ensure that the dose is delivered as intended and that participants are extended to their outer edge of communicative competence. There was no indication of treatment effect in the clinical data collected and there may have been some negative effect for those who received a course of ILAT. The absence of treatment effect may well be attributable to a Type II error, reflecting the play of chance in the small sample size. Furthermore, the primary outcome measures may not have been sensitive enough to measure change. Also, there needs to be further evaluation of the mechanism of action to determine if the components of ILAT do in fact activate Hebbian learning.

The purpose of this pilot trial was to determine the feasibility and acceptability of evaluating assistant/volunteer facilitated ILAT with in a RCT and the progression criteria demonstrating this were all met within the pilot trial. A larger sample size would allow for subgroup analysis (different aphasia profile and severity levels to be analysed) to determine if there is a type of aphasia that benefits from ILAT and if there are some types of aphasia that do not benefit from treatment with ILAT. However, outcome measure assessment, acceptability and delivery of intended dose give pause to suggesting a definitive trial should be attempted without further preliminary research. Further investigation of the primary outcome measure is needed to ensure that any changes in conversational ability are captured by the outcome measure. Also changes to the treatment schedule and training manual need to be completed and trialled to ensure participants receive the intended dose and are extended to the best of their communication ability.

7.6 Considerations for conducting a definitive trial

The following section discusses potential challenges and proposes possible solutions for the delivery of a definitive trial of assistant/volunteer facilitated ILAT.

7.6.1 Sample size for a definitive trial

Due to the intra-cluster correlation coefficient (ICC) inflation factor of 2.46 (calculated using the 4-month outcome TOM's activity scale ICC of 0.487) the total sample would be 329 participants. This sample size is comprised of 95 participants per arm with the ICC inflation factor of 2.46 increasing the ILAT arm to 234. This pilot trial has demonstrated that recruitment of the required

sample size for a full trial from the relevant population would be challenging as this is a large sample size for the population of people with aphasia. Further inflating this sample size to 468 may well make this study impossible to complete. Other studies completed with populations of people with aphasia that also examined usual care have not inflated the sample size to control for a therapist effect (211,242). Therefore, given the difficulty that recruiting to study with a sample of size of 468 would pose perhaps it is more sensible to only inflate the treatment arm therefore, controlling the therapist effect caused by treating participants in groups but not inflating the sample size to an unmanageable amount.

In the pilot 28 participants were recruited in 16 months which is slightly higher than other studies recruitment rates in populations of people with aphasia (201). Four courses of ILAT were completed with four participants per course. Across the four courses of ILAT it was decided the fidelity of ILAT was maintained better with courses of three participants. To achieve the estimated sample size of 329 participants for a definitive trial of ILAT between 19 and 36 sites would need to be recruited depending on the number of courses being run at each site. It may be beneficial to obtain an agreement per site on the number of courses of ILAT, ranging from two to four courses, each site could commit to run based on the known population of people with aphasia at any one time at each site. Table 49 shows the number of sites required given the number of ILAT courses delivered ranging from two to four.

Table 49 Number of sites required per number of courses of ILAT

	4 courses	3 courses	2 courses
No. for ILAT	12	9	6
No. for Usual care	6	4/5	3
Total no. participants per site	18	13/14	9
Total no. of sites	19	24	37
Total no. participants	342	336	333

If sites were able to complete four courses of ILAT, as was achieved in the pilot, then 18 (12 ILAT and 6 usual care) participants would be required per site needing 19 sites to reach the estimated sample size. Conversely, if only two courses were completed then nine participants would be required per site needing 36 sites to reach the estimated sample size. Setting the recruitment per site at 18 participants would increase the length of the trial which inflates the fixed costs of completing the trial. Having more centres will allow the recruitment time to be shorter thus reducing the fixed costs. In a definitive trial targeting the same population of people with

aphasia in the UK, 279 people with aphasia were recruited in 15 months across 21 sites. Recruitment ranged from seven to 22 participants per site with a median of 12 participants per site (211). Therefore, the most realistic recruitment target may be 24 or more sites recruiting 14 participants per site which would result in the completion of three courses of ILAT per site.

A recruitment rate of one participant per month has been demonstrated in other studies assessing the population of people with aphasia (211,236). Therefore depending on the number of sites and the number of participants recruited per site, a period of between nine (37 sites recruiting nine participants per site) to 18 (19 sites recruiting 18 participants per site) months would be required to reach the estimated sample size. The recruitment rate in this pilot was 1.87 participants per month.

At least 12 months would be required to gain the necessary approvals and set up this large number of sites. Additional time should be allocated to allow the recruitment of further sites, if necessary, once the prevalent population at each site has been exhausted. As the population of people with aphasia is only slowly replenished once the prevalent population has been approached then extending the period of recruitment would result in diminishing recruitment rate. Therefore, opening another site may be more beneficial than extending the time at a particular site.

7.6.2 Excess treatment costs

Excess treatment costs to support the delivery of ILAT were subsumed by the NHS trust where the pilot RCT was completed. This is unlikely to be the case for sites in a definitive trial. Palmer et al. (2016) found negotiating the payment of excess treatment cost varied across the 21 sites recruited to the study and that significant delays of up to 18 weeks were found. This inconsistency was found to delay recruitment. Palmer et al (2016) also found that the negotiations required the time and expertise of a senior trial manager (243). Therefore, this definitive trial would need to allow time and allocate resources to complete the negotiation of excess treatment costs with each site.

7.6.3 Suggested model for recruitment and treatment

This pilot was conducted in the research SLTs home NHS trust and as such there was an increased amount of support given to the pilot than what could be expected from sites in a possible definitive trial. The research SLT was of course highly motivated to recruit to and

complete the desired number of ILAT courses and NHS management agreed to releasing assistant time to support the pilot perhaps more readily than would be achieved at multiple sites participating in a definitive trial. These factors may influence the generalisability of the pilot trial to a definitive trial (233).

A recent definitive RCT for aphasia provided some suggestions for improving recruitment in studies for aphasia which were; using a stepped approach to consent (which was also trialled in this pilot), use of the consent support tool, use carer/relative declaration to allow participation for those unable to consent (all trialled in this pilot) also being available for support at the central research team, providing monthly newsletters which provided an element of competition to improve recruitment and providing funding to allow SLTs to dedicate time to the recruitment of participants (211). Therefore, a proposed model for recruitment and treatment in a definitive trial could be releasing SLTs to perform a primary investigator role that included recruiting participants, training and supervising assistants and volunteers. These roles are best completed by an SLT as they are integrated into the team of SLTs that will be identifying and referring potential participants, the SLT themselves will be aware of and familiar to some of the potential participants. An SLT has, as part of the general training the skills and experience of communicating with people with aphasia and will be able to communicate the trial information in aphasia friendly format as well as perform outcome measures.

As was completed in this pilot trial, participants will be randomised in batches meaning the outcome assessments will need to be completed in batches. This will result in six participants requiring outcome assessment within one month that these become due and then none in the following months until the next batch is due. This differs from other trials of people with aphasia where one or two participants are randomised per month and then the same number are due outcome assessment per month and therefore requires suitable resourcing of outcome assessors to ensure timely collection of outcomes.

Speech and Language Therapists deliver training to assistants/volunteers in usual practice but did not supervise ILAT facilitated by the assistants/volunteers in this pilot. A training manual for this process was developed as part of this PhD. The research SLT would need to train each sites' SLT primary investigator to complete the training and supervision role. SLTs may never have delivered ILAT themselves and the specific needs of SLTs in this role would need to be explored. Training could be conducted centrally as sites are set up and would include training on the

components of ILAT as well as practical experience delivering ILAT. People with aphasia from a patient and public advisory group could attend a session so that SLTs can gain experience facilitating ILAT before being expected to supervise assistants/volunteers in this role. As such the SLTs would be participants in a definitive trial and fidelity of their roles in training and supervision would need to be monitored.

7.6.4 Refinement of assistant/volunteer facilitated ILAT delivery model

It was difficult to recruit volunteers to the role of facilitators nevertheless, where this occurred it worked well and relieved the pressure of delivering ILAT on the therapy department. I think it would still be feasible to recruit volunteers and there was enough time to recruit, train and complete procedures to ensure compliance with trust policy regarding criminal records checking and occupational health checks etc. whilst participants were also being recruited. However, the bulk of the facilitator role during the pilot trial was completed by assistants with volunteers supplementing the load. Therefore, where volunteers are available it is beneficial to use them, but sites should consider that the bulk of the resource to facilitate ILAT would best be met by assistant staff time.

From the findings of the pilot trial the courses of ILAT that ran most smoothly were supported by one key assistant with the secondary facilitator each day being another assistant or volunteer. This consistency supported the continuity of care for the participants and ensured that facilitators had an adequate handover from the previous day. Therefore, it would be beneficial if sites that are recruited to a definitive trial would agree to an assistant being allocated to the research project whilst the remaining facilitator time could be filled by other assistants and volunteers.

7.6.5 Economic evaluation of assistant/volunteer facilitated ILAT

Economic evaluation of assistant/volunteer facilitated ILAT compared to usual care is needed to determine whether assistant/volunteer facilitated ILAT is an efficient and cost-effective intervention for aphasia.

The total cost estimate of assistant/volunteer facilitated ILAT was not completed in this study. It is really important to determine the cost of SLT time used for training and supervision as well as the cost of assistant time for delivering ILAT compared to usual care within the NHS to determine whether assistant/volunteer facilitated ILAT is in fact efficient to deliver. Some of the

data that is required to begin to assess this cost was collected during this pilot trial but no record was kept of the resource cost of training assistants/volunteers so this estimate is not available for evaluation here. These evaluations would be essential in determining if assistant/volunteer facilitated ILAT is a cost effective intervention for the NHS.

7.7 Implications for clinicians, patients, policy makers, other stakeholders

Participants reported ILAT was acceptable when facilitated by assistants/volunteers. There was no mention of dissatisfaction that the SLT was not delivering the intervention directly. Assistants/volunteers also felt comfortable preforming the role of facilitators and found the it rewarding and challenging. There is therefore an opportunity with this method to establish roles particularly for assistants within SLT departments to take on a specialised role of facilitating group interventions for aphasia to help deliver more therapy without the need for additional qualified SLT resources. Volunteers however found delivering group therapy more difficult and the role may not be as appropriate for them independently of an SLT.

However, as this study did not identify any efficacy signal for ILAT specifically, it would be premature for clinicians to offer the specific group therapy ILAT facilitated by assistants/volunteers in favour of current guidance and results of further research should be awaited.

7.8 Further research

This trial did not examine the underlying mechanism of action, Hebbian learning through the utilisation of imaging techniques. Hebbian learning is hypothesized to be the mechanism of action, but there is not yet any evidence to confirm that the components of ILAT do indeed work through this mechanism of action. As there was no signal in the data to indicate that Hebbian learning was activated it would be useful to consider if imaging could identify if this mechanism was activated. Therefore, including imaging techniques in the outcome assessment of ILAT might help to examine what is happening neurologically following a course of assistant/volunteer facilitated ILAT.

The individual components of ILAT; language action embedding, intensity/massed practice, constraint/focusing, shaping and tailoring have not yet been evaluated independently to determine which of the components contribute to the anticipated treatment effect. Some research has been completed examining the components of massed practice (77) and research

examining constraint/focusing is underway (132). However, further research is needed to examine the components of language action embedding, and shaping and tailoring require further examination individually but also research needs to establish what of these components are essential to activate Hebbian learning.

To this end, the COMPARE study (Constraint-induced or multi-modal personalized aphasia rehabilitation (COMPARE): A randomized controlled trial for stroke-related chronic aphasia) by Rose et al. (2019) is in progress which is evaluating ILAT compared to an unconstrained intervention (M-MAT) to determine the impact of constraint or focusing on speech to achieve outcomes for aphasia. Also, Stahl et al. (2018) compared different intensities of ILAT to determine the effect of massed practice on the communication outcomes following ILAT.

In this pilot trial assistants/volunteers did not manage to deliver the intended dose and furthermore both volunteers and some participants found the intensity challenging. However, more recent literature suggests that treatment beyond 20 hours does not provide additional benefit (77), therefore we could consider reducing the intended dose in the treatment protocol and pilot this reduced dose prior to a completing a definitive trial.

Finally, the outcome measures, particularly the TOM's, may not be the most appropriate or sensitive outcome measure to assess changes in conversation following treatment with ILAT. Also, piloting of the outcome measures suggested for aphasia research (200) including the Western Aphasia Battery and the SaQOL need to be piloted to measure the outcomes following ILAT.

7.9 Conclusions

Intensive Language Action Therapy (ILAT) was identified as an intervention that had been delivered intensively, efficiently both in a group and facilitated by laypersons, and had the best available evidence. Components of ILAT were identified that target the principles of experience-dependent learning that are believed to trigger the proposed mechanism of Hebbian learning. A programme theory and logic model were developed to describe how ILAT worked along with a manual to describe delivery by assistants and volunteers for an NHS setting. A pilot study then confirmed feasibility of conducting a randomised controlled trial of assistant/volunteer led ILAT versus usual care in NHS settings. Facilitation by assistants and volunteers was found to be acceptable and generally feasible with good fidelity to delivery of most aspects of the

intervention. However, fidelity to the provision of the target therapy dose and to prompting patients to expand their language use was poor. Although qualitative interviews identified perception of individual clinical improvements, there was no indication of clinical benefit of ILAT delivered by assistants/volunteers from the quantitative data. Further research is required to attempt to fully understand what impact each component of ILAT is having on the intended outcomes and on clearly defining those components and how they must be delivered. Outcome measure assessment, acceptability and delivery of intended dose require further preliminary research before suggesting a definitive trial should be attempted. The work in this thesis has made a first contribution to developing and evaluating an efficient way of delivering ILAT as an intensive conversation therapy in the NHS.

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Appendices

Appendix 1 Search Strategy full terms

The following search strategy was used for Medline and repeated in CINHL and PsycINFO.

1. Stroke, OR Stroke rehabilitation OR stroke.mp
2. Aphasia, aphasia Broca OR Aphasia Wernicke OR Aphasia, Conduction OR aphasia.mp
3. 1 AND 2
4. Rehabilitation. Mp OR Neurological rehabilitation, OR Rehabilitation Research, OR Stroke Rehabilitation, OR Intervention.mp
5. 3 AND 4
6. Meta-analysis.mp.pt, OR review.pt, OR systematic review, OR search:.tw
7. 5 AND 6

Appendix 2 Excluded Reviews

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Appendix 3 Redundancy of Randomised Controlled trials extracted from systematic reviews compared to the Cochrane review *(28)*

Systematic review	Randomised Control Trials	Brady et al, 2016
Allen et al, 2014	Elman &Bernstien-Ellis, 1999	+
	Kagan et al, 2001	-
	Di Carlo, 1980	+
	Doesborgh et al, 2004	+
	Katz & Wertz, 1997	+
	Cherney et al, 2010	+
	Palmer et al, 2012	+
	Nobis-Bosch et al, 2011	+
	Meinzer et al, 2007	+
	Pulvermuller et al, 2001	+
Balardin and Miotto, 2009	Pulvermuller et al 2001	+
	Meinzer et al, 2007	+
Bohgal, 2003	Lincoln et al, 1984	+
	Wertz et al, 1986	+
	Hartman & Landau, 1987	-
	David et al, 1982	+
	Prins et al, 1989	+
Bohgal, Teasell & Speechley, 2003	David et al, 1982	+
	Lincoln, et al, 1984	+
	Wertz et al, 1986	+
	Hartman & Landau, 1987	-
	Prins, et al, 1989	+
	Meikle et al, 1979	+
	Shewan &Kertesz, 1984	+
Cherney et al, 2008	Hinckley & Carr, 2005	-
	Meinzer et al, 2005	-
	Pulvermuler, et al, 2001	+
Cicerone, et al, 2011	Bakheit, et al, 2007	+
	Doesborgh, et al, 2004	+
	Hinckley & Carr, 2005	-
	Meinzer, et al, 2005	-
Hurkmans, et al, 2012	No RCT's reported	**N/A**
Lanyon, Rose & Worrall, 2013	Elman & Bernstien-Ellis, 1999	+
	Meinzer, et al, 2007	+
	Pulvermuller, et al, 2001	+
Lavoie, Macoir & Brier, 2017*	Doesborgh, et al, 2004	+
	Palmer, et al, 2012	+
Rose, et al, 2013	No RCT's reported	**N/A**
Robey, 1998	No RCT's reported	**N/A**
Simmons-Mackie, et al, 2016*	Kagan, et al, 2001	-
	Lyon, Cariski & Keisler, 1997	+
Zhang, et al, 2017*	Pulvermuller et al, 2001	+
	Szaflarski, et al, 2014	+

	Woldag, et al, 2017	- (Published after Brady et al, 2016)
	Sickert, et al, 2013	+
	Wilssens, et al, 2015	+
	Ciccone, et al, 2015	+

* reviews identified in updated search conducted in April 2020

Appendix 4 Redundancy of aphasia interventions identified in randomised and non-randomised study designs in non-Cochrane systematic reviews compared with the Cochrane review *(28)*

Interventions identified from non-Cochrane systematic reviews	**Included in Brady, et al, 2016**
Semantic therapies Semantic Feature Analysis(48), BOX(49) Semantic complexity training , contextual priming, word to picture matching, semantic judgments, naming therapies	+
Phonological therapies Phonemic cues, Repetition	+
Reading therapies (91)	+
Writing therapies	+
Verb therapies(94)	+
Syntax training (95) Preposition therapy	+
Melodic Intonation Therapy(104) SIPARI	+
Constraint Induced Aphasia Therapy/Intensive Language Action Therapy(55)	+
Multimodality Aphasia therapy (56)	+*
Promoting Aphasic Communicative Effectiveness (106)	+
Computer based therapies Step by Step(101), REACT(102), Aphasia therapy online(103)	+
Compensatory training, total communication	+
Alternative and Augmentative Communication (96)	+
Supported conversation (98)	+
Script training (97) ORLA(92)	+
Reciprocal scaffolding(107)	+
Response Elaboration Training (108)	+
Conversation Partner Training (98) Conversational coaching (99)	+
Support and Social Stimulation	+
Psychological and emotional support(100)	+
Gestural therapies (85)	+
Functional communication therapies, Key Word Training, context based treatment(89)	+
Narrative therapies NARNIA, picture description	+
Comprehension therapies, Sentence Mapping Intervention	+
Cognitive Linguistic Therapy (105)	+
Comprehension therapies (234)	+

Foot note *identified in the on-going trials listed in the Cochrane review (28)

Appendix 5 GRADE assessment of the evidence on functional communication outcomes for included interventions compared to other SLT from Cochrane review *(28)*

Outcomes	SLT comparison	No. of participants (trials)	Relative effect (95% CI)	Direction of effect	Quality of the evidence (GRADE)
Functional Communication	Constraint-Induced Aphasia therapy vs other SLT	126 participants (3 trials)	SMD: 0.15 (-0.21-0.50)	No evidence of benefit or harm	□□ Low

Appendix 6 Full list of Search terms and strategy

1. Aphasia.mp. or exp Aphasia, Broca/ or exp Aphasia, Wernicke/ or exp Aphasia/ or exp Aphasia, Conduction/
2. dysphasia.mp.
3. 1 or 2
4. exp Stroke, Lacunar/ or exp Stroke/ or stroke.mp.
5. exp Chronic Disease/px, rh, th [Psychology, Rehabilitation, Therapy]
6. 4 or 5
7. Speech therapy.mp. or exp Speech Therapy/
8. language therapy.mp. or exp Language Therapy/
9. Speech-language pathology.mp. or exp Speech-Language Pathology/
10. 7 or 8 or 9
11. 3 and 6 and 10
12. exp Group Processes/
13. group.mp.
14. 12 or 13
15. 11 and 14
15. intensive.mp.
17. 11 and 16
18. 15 and 16

Appendix 7 TIDieR checklist

The TIDieR (Template for Intervention Description and Replication) Checklist*:

TIDieR
Template for Intervention Description and Replication

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	_____	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	_____	_____
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	_____	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	_____	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the	_____	_____

	course of the study, describe the changes (what, why, when, and how). **HOW WELL**		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	_____	_____
12.†	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	_____	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).
‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.
* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Appendix 8 Daily Intervention Log
Final version of the Daily Intervention Log

ILAT
Pilot

Daily intervention log

IP ☐/☐☐☐
Participant initials ☐☐

ILAT
Pilot

Daily intervention log

IP ☐/☐☐☐

Participant initials ☐☐☐

LAG 6

Card set ☐☐☐ Type ☐ Planning ☐ Request Duration ☐☐ mins

Player turns

#	Rule complexity* (tick one box only)					Rule components† (tick all that apply)			Appropriateness† (tick one box only)				Clarification questions (keep a tally)	Prompts required§ (tick all that apply OR *None*)					Notes
	Any	SW	2WP	SGS	CGS	CP	PN	P	0	1	2	3		C	FS	PC	R	*None*	
1	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	
2	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	
3	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	
4	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	
5	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	
6	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	
7	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	
8	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	
9	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	
10	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐		☐	☐	☐	☐	☐	

* **Any** Any utterance
SW Single words
2WP 2 word phrase
SGS Single grammatical sentence
CGS Complex grammatical sentence

† **CP** Carrier phrase
PN Player's name
P Politeness

† **0** Not functional at all
1 Minor functional contribution
2 Functional minor delay
3 Fully functional

§ **C** Clue (semantic)
FS First sound (phonemic)
PC Phrase completion
R Repetition

Comments

Version 1 trialled with first ILAT course

LAG 1

Card set ☐☐☐ Type ☐ Planning ☐ Request Duration ☐☐ mins

Player turns

#	Rule complexity* (circle one only)	Rule components† (circle all that apply)	Appropriateness† (circle one only)	Clarification questions (keep a tally)	Prompts required§ (circle all that apply)	Notes
1	Any SW 2WP SGS CGS	CP PN P	0 1 2 3		S P PC R N	
2	Any SW 2WP SGS CGS	CP PN P	0 1 2 3		S P PC R N	
3	Any SW 2WP SGS CGS	CP PN P	0 1 2 3		S P PC R N	
4	Any SW 2WP SGS CGS	CP PN P	0 1 2 3		S P PC R N	
5	Any SW 2WP SGS CGS	CP PN P	0 1 2 3		S P PC R N	
6	Any SW 2WP SGS CGS	CP PN P	0 1 2 3		S P PC R N	
7	Any SW 2WP SGS CGS	CP PN P	0 1 2 3		S P PC R N	
8	Any SW 2WP SGS CGS	CP PN P	0 1 2 3		S P PC R N	
9	Any SW 2WP SGS CGS	CP PN P	0 1 2 3		S P PC R N	
10	Any SW 2WP SGS CGS	CP PN P	0 1 2 3		S P PC R N	

*Any Any utterance
SW Single words
2WP 2 word phrase
SGS Single grammatical sentence
CGS Complex grammatical sentence

†CP Carrier phrase
PN Player's name
P Politeness

‡0 Not functional at all
1 Minor functional contribution
2 Functional minor delay
3 Fully functional

§ S Semantic
P Phonemic
PC Phrase completion
R Repetition OR
N None

Version 2 trialled with ILAT course 1

LAG 1

Card set ☐☐☐ Type ☐ Planning ☐ Request Duration ☐☐ mins

Player turns

#	Rule complexity* (tick one box only)	Rule components† (tick all that apply)	Appropriateness† (tick one box only)	Clarification questions (keep a tally)	Prompts required§ (tick all that apply)	Notes
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

*Any Any utterance
SW Single words
2WP 2 word phrase
SGS Single grammatical sentence
CGS Complex grammatical sentence

† CP Carrier phrase
PN Player's name
P Politeness

‡ 0 Not functional at all
1 Minor functional contribution
2 Functional minor delay
3 Fully functional

§ S Semantic
P Phonemic
PC Phrase completion
R Repetition OR
N None

Example of tailored intervention log

ILAT
Pilot

Daily intervention log

IP ☐ / ☐☐☐

Participant initials ☐

Date ☐☐ ☐☐ ☐☐☐☐
d d m m y y y y

Session number ☐☐

Attended ☐ Yes ☐ No

Facilitator 1 ______

Facilitator 2 ______

Individual target rules

Complexity
(Please tick one box only)

- ☐ Any utterance
- ☐ Single words
- ☐ 2 word phrase (adjective/noun or noun/verb)
- ☑ Simple grammatical sentence
- ☐ Complex grammatical sentence

Components
(Please tick all that apply)

- ☑ Carrier phrase
- ☑ Player's name
- ☑ Politeness

Additional details

Encourage the use of at least 2 descriptive words eg. Please may I have the two small red apples?

Northern Lincolnshire and Goole NHS
NHS Foundation Trust

The University Of Sheffield.

Contents

Introduction

This manual has been developed with reference to other manuals for use by non-Speech and Language Therapists working with people with aphasia and group therapies. This manual is intended to support Speech and Language Therapists implementing Intensive Language Action Therapy using Speech and Language Therapy Assistants and volunteers in the National Health Service. An assistant/volunteer hand book is attached to support the delivery of Intensive Language Action Therapy.

Background

Aphasia is an acquired language disorder and is a common and devastating consequence of stroke (RCSLT, 2009). People with aphasia typically receive speech and language therapy (Brady, et al, 2016). Research suggests that people with aphasia achieve the most improvement when therapy is delivered intensively. However intensively delivered therapy requires more therapist time than current NHS resources

allow. It is therefore necessary to provide efficient and affordable treatment options. Non-Speech Therapists have been successfully employed to facilitate therapy activities (Bowen et al, 2012, Palmer et al, 2012).

Intensive Language Action Therapy

Intensive Language Action Therapy (ILAT) is an intensively delivered therapy that aims to improve the ability of people with aphasia to speak and has shown to be a promising intervention through preliminary research studies (Cherney et al, 2010). ILAT aims to improve conversation, the ability to name words and repair communication where it has failed. Pullvermuler, (2001) also suggests that ILAT improves receptive language abilities due to the prolonged periods of attention and exposure to language during the therapy. ILAT is a group therapy. 3-4 people with aphasia of similar severity need to be grouped together. Therapy sessions happen 5 days a week for 2 weeks. Participants practice using increasing amounts of language to make requests in group barrier games as therapy progresses. Use of other means of communication such as gesture or pointing are restricted to focus on spoken language use. Speech and language therapy (SLT) or therapy assistants or volunteers may be able to deliver ILAT under the supervision of a SLT (Meinzer, et al, 2007), which would reduce the resources needed to provide this intensive therapy and therefore make it available on the NHS.

ILAT is provided face-to-face with two facilitators either therapy assistants or volunteers. ILAT uses card exchange games where participants take turns to request cards from co-players (Pulvermuller, et al, 2001). Screens are placed between participants to prevent the use of nonverbal communication methods. A facilitator (assistant or volunteer) acts as a co-player to model the target language. Also this facilitator asks questions to try and help co-players with aphasia to correctly request cards. For example questions and scripts of exchanges please see the Appendix B. Another facilitator ensures the game runs smoothly providing cues when participants struggle with word finding. Facilitators complete a Daily Intervention Log to allow feedback to the supervising SLT.

Key principles underpinning ILAT

ILAT is based on several neuroscience principles.

- Intensive and Repetitive practice: ILAT is intensively delivered and massed into 30 hours of therapy delivered across 10 days providing intensive and repetitive practice.

- Shaping: Responses gradually increase in complexity and are reinforced using shaping.

- Social imperative to communicate: The interactive group therapy approach provides the behavioral relevance required for salience and transference that should result in generalisation. Placing the players of the game into the context of the game and providing words that are relevant to day to day life ensures the therapy is behaviorally relevant.

- Learned non-use: ILAT constraints the use of non-verbal forms of communication using screens encouraging only spoken output. Therefore, discouraging learned non-use following the notion of 'use it or lose it'

Development of ILAT

ILAT was developed by Professor Pulvermuller and first published in the literature in 2001 under the name Constraint Induced Aphasia Therapy. Professor Pulvermuller took the principles of Constraint Induced Movement Therapy; constraint, shaping, and massed practice, and applied these to language and use and recovery for aphasia following stroke. Constraint Induced Movement Therapy advocated the restriction of the non-effected upper limb using a sling or glove for several hours a day to force the use of the effected limb. Professor Pulvermuller stated that the same could be achieved in the production of speech through the restriction of non-oral forms of communication such as gesture and pointing. Initially this was achieved using screens between players and active discouragement by facilitators to prevent gesture during therapy. However, further evidence developed that suggested that gesture may in fact support people with aphasia to retrieve spoken words and consequently the protocol for the delivery of therapy was softened to allow gesture with the continued emphasis that spoken output would still only be accepted as correct during the therapy. This shift in focus also came with the name change to Intensive Language Action Therapy.

In its original form CIAT only reported the use of repetition of desired output and did not give explicit details about the cueing given to participants to achieve the desired output. However, in the descriptions of ILAT it has become clear that all forms of cueing for example, semantic, phonemic and orthographic cues are acceptable in the delivery of ILAT.

Therefore, in the delivery of ILAT we encourage the use of gesture, phonemic, semantic, orthographic and repetition/modelling cues to support the successful spoken output.

Speech and Language Therapist (SLT) Role

Assessment and tailoring

A Speech and Language Therapist is required to complete a detailed assessment of the patient's language profile to tailor the ILAT individual game rules and materials so that ILAT targets the specific difficulties identified.

Supervision

Also, a SLT is required to monitor the progress of each participant each day to further modify the individual rules and materials so that each patient is always communicating to the best of their ability.

Therapy Assistant and Volunteer Role

The assistant and volunteer and responsible for the everyday running of the group following the individual plans provided by the SLT. Assistants and volunteers also need to complete the Daily Intervention Log and provide feedback to the SLT. Please see Assistant and Volunteer Handbook for details.

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Appendix A

Northern Lincolnshire and Goole NHS
NHS Foundation Trust

The University Of Sheffield.

Contents

About Stroke

Stroke is a sudden loss of blood supply to the brain. It can be caused be either a blockage (infarct) in a blood vessel or by a rupture (haemorrhage) to a blood vessel. Both a blockage and rupture mean that the nutrients required to keep brain cells alive is lost causing brain cells to die.

What is Aphasia?

Aphasia is a devastating consequence of damage, often caused by stroke, to the parts of the brain that are responsible for using and understanding language.

Someone with Aphasia may find it difficult or impossible to talk, listen, understand, write, read or use numbers. These problems with communication make it difficult or impossible for people with Aphasia to complete every day activities like, making a telephone call, following a television program or joining in a conversation.

Aphasia is complex and affects each person differently. For some people with Aphasia communication might be almost normal and for others it may be very difficult. Things like tiredness, stress and illness can make Aphasia worse.

Having Aphasia is often frustrating and can cause people to be isolated. Roles with in families and friendships may change which can cause strain and relationships to breakdown. People under retirement age with Aphasia are often unable to return to work resulting in loss of status, sense of self and financial security.

What is Intensive Language Action Therapy (ILAT)?

ILAT is a group therapy. Three or four people with aphasia form a group to complete a course of ILAT.

Duration

Each course runs for 10 sessions on 10 working days (Monday-Friday). Each session lasts for 4 hours with 3 hours of therapy, 2 tea/coffee breaks and 1 lunch break (see daily schedule for details, page 6).

Language Action Games

During in the 3 hours of therapy the people with aphasia will play Language Action Games (LAG's). LAG's are card exchange games like Old Maid or Guess Who? Each player is dealt several cards from a card set (see materials for details of card sets, page 7) and then try to find matching pairs of cards by requesting them from other players. Players must speak clearly and correctly to make sure they are given the correctly matching card. To prevent players from looking at each other's cards or from gesturing or pointing screens are placed between the players. Each player will request a card in turn until all the cards are matched. Please aim for each LAG to take about 1 hour to complete. If the players are very fast and the LAG ends quickly deal another round of cards and continue to play until the hour is reached.

Individual Rules

Each player will have an individual Daily Intervention Log (see Appendix 2) that shows how to make the requests for cards. For example, a player whose aphasia makes it hard for them to say individual words clearly will only be required to clearly and correctly say a single word describing a card. Whereas a player who can speak in short sentences will be required to say the other players name, a sentence such 'do you have the…' and the name of the item on the card. The individual rules will be set by the Speech and Language Therapist and recorded on the Daily Intervention Log for each day of therapy. For a list of the individual rules please see the Daily Intervention Log.

Facilitators

Two facilitators will also be running a ILAT session. One facilitator will play the game. The facilitator playing the game is being a good example and is showing all the other players how to make requests. This facilitator should also ask questions to clarify when players with aphasia make unclear requests (see Appendix 1 for examples). Another facilitator should record each player's turn on the Daily Intervention Log. Players may have difficulty saying a word or sentence clearly and might require some clues from a facilitator. First the facilitator, or another player will ask some questions to try and clarify the request. Questions such as;

- Where would you find it?
- How do you use it?
- When would you do it?

If these questions do not clarify the request then two choices can be given such as;

- Is it inside or outside?
- Is it big or small?
- Is it for work or fun? (see appendix 1 for more examples)

The facilitators will know what kind of questions to ask based on the pictures that are being used for the LAG.

If the request can't be sorted using the questions above then the following list of prompts may be used to help each player:

1. Clue - Give an example of what type of thing it is or what category it belongs to for example, an animal if the item is a cat or something you eat with if the item is a fork
2. First Sound clue – Give the first sound in the word for example, it starts with /f/ for the item fork
3. Phrase completion – put the word into a phrase or sentence but don't say the items name for example, knife and …

4. Repetition – quietly tell the player what the item and is and ask them to try and repeat it so that the other players can hear

Players must be given plenty of time to think about the card and to try and say the required word or sentence before facilitators ask any questions or give any clues. If a player is struggling wait patiently until they indicate they would like some help or if they become frustrated. If a player makes a mistake by saying the wrong word for example saying knife instead of fork or the sounds in the word are wrong saying "tork" instead of "fork", then the facilitator could say something like 'oops that's not quite right, try again'. If the player is unable to correctly and clearly say the word or sentence, then the facilitator can give the clues to help the player say it correctly and clearly. If a player is required to say a sentence or another players name and forgets, then the facilitator can give the player a reminder of the rules. Make sure you are encouraging throughout the LAGs giving praise when players do well and encouraging players who are struggling.

Breaks

After playing a LAG for 1 hour please give the players a break. One morning tea break, one lunch break and one afternoon tea break. Tea and coffee supplies and biscuits will be available. Please offer each player refreshments and please feel free to have some refreshments yourself. Each tea break should last 15 minutes and the lunch break should last 30 minutes. During these breaks remove the screens from the table. Please sit down with the players and have a chat. Encourage all players to join in the conversations. Also, encourage all players to use whatever means of communication they usually use for example, gesture, writing, drawing, communication books etc. The break time is an important time for players and facilitators to get to know one another and to practice making conversations in a normal way.

Supervision and Feedback

During the sessions, the research SLT will be available to contact via the phone should any difficulties arise. Some of the sessions will be observed by the research SLT to make sure facilitators are confident with all roles and responsibilities required.

Completing the Daily Intervention Log

Facilitators need to complete the Daily Intervention Log (DIL) throughout each LAG and make sure it is fully completed by the end of the session. There is a separate DIL for each player and each day. The DIL will tell you the individual target rules for each player. On each player's individual DIL you will need to complete the table for each turn taken, marking down if the target rules were followed, the appropriateness of the response (a scale of 1-3 See Appendix 2 for examples of scoring) and record any prompts given to the player. Please record the number of minutes each LAG lasted. There is also space to write any notes you may want to tell the SLT after the session.

The research SLT will then meet with the facilitators to look through each players DIL, discuss how the session went and set out the individual rules for each player for the next day.

Daily Schedule

9:45 Set up room, check materials

10:00 Patients arrive

10:15 Begin first Language Action Game *(aim to play for one hour, if the game is short re-deal and play another round, if the game is long cut it short to ensure a break is given)*

11:15 Tea break – provide refreshments and comfort break

11:30 Second Language Action Game

12:30 Lunch Break *(use this time to encourage patients to have conversations and support each patient to participate as possible)*

13:00 Final Language Action Game

14:00 Patients leave, pack up equipment, finalise Daily Intervention Logs

14:15 Supervision with SLT

14:45 Finish

Room Set Up

You will need to arrange a small table with four chairs in the centre of the room. Place the screens provided on top of the table to prevent patients from seeing each other's cards. Collect and set up the tea/coffee supplies and fill the kettle. If working in the triage room, please turn on the heater if it is cold.

Materials

There are different packs of cards that can be used for each session. The Speech and Language Therapist will indicate on the Daily Intervention Log which packs to use for each day.

Frequent Words: This is the simplest level of cards. Three sets of this level are available for use during LAG's. These cards represent single objects that are frequently used in everyday life. The sets in this level are labelled FW 1-3.

Minimal Pairs: These cards show objects that differ by only one sound. For example, 'ball' and 'wall'; or 'glass' and 'grass'. Patients must say each word very clearly to correctly name each object. This level of cards is labelled MP and has only one set.

Semantic Categories: These cards show things that belong together in a category such as animals, clothing, furniture or tools. These categories require patients to more accurately name the item. For example, if an animal set is being used then a patient might say 'animal' or 'animal with four legs'. However, if there is a picture of a dog, cat and cow then 'animal' or 'animal with four legs' would not provide enough information to allow the correct identification of the item. This level of cards is labelled SC 1-7. There are only 12 cards in each set for this level so it will be necessary to combine 2 sets to use for a LAG.

Multi feature objects: This level of cards show objects that differ in number, colour, shape or size. For example, a card may show four round biscuits where other cards in the set may show three biscuits or square biscuits. This level of cards requires patients to use two or three words to successfully identify an item. These cards are labelled MF 1-6.

Spatial relationships: This level of cards show objects that are arranged in different ways. For example, a card may show a cup *on* a saucer whilst another shows a cup *under* a saucer or a cup *next to* a saucer. This level of cards is labelled SR 1 and SR 2.

Action Cards: This level of cards show actions such as brushing teeth or playing a board game. These items require patients to use doing words or verbs. This level of cards can also be used for the Planning LAG and are labelled Ac 1 and Ac 2.

APPENDIX B

Examples of questions for use in Language Action Games

Is it big or small?
Is it inside of outside?
Is it something to eat or drink?
Is it in the house or an office?
Is it a wild or domestic animal?
Would you see it in the day or the night?
Are there lots of or only one?
Is it red or blue?
Is it for work or fun?
Is it for your hands or feet?
Is the person happy or sad?

As you will have cards in front of you, use those to help you think of questions you could ask to find out more from the player making the request.

Examples of 2 word phrases

Pass clock?
Red apple?
Big dog?

Examples of Simple Grammatical Sentence

Could you pass me the clock?
Do you have the red apple?
Can I have the big dog?

Examples of Complex Grammatical Sentence

Could you pass me the clock that reads 4pm?
Do you have the apple that is red?
Can I have the big, brown dog that is playing with a stick in the garden?

Examples of politeness

Pass the clock? (no politeness)
Please could you pass the clock? (politeness required)

Examples of player name

Could you pass me the clock? (no player name)
Jane, could you pass me the clock? (player name)

Example Scripts of Language Action Games

REQUESTS

Transcript 1
A: Do you have the apple?
B: Is the apple red or green?
A: Green
B: No sorry I don't have a green apple?
A: Do you have the apple?
C: Do you mean the green apple? Yes I have it. (Player C shows and hands Player A the card)

Transcript 2 clarifying the request (Difrancesco and Pullvermuller, 2012)
A: Right, err, do you – err, crow, crow something, err right
B: What colour is it Player A?
A Its blue, blue on one side and red at the back and red at the front, and its clo- crow hammer, hammer. Have you got it?
B: Does it have one handle or two handles?
A: Err, no- not really, Not really a handle.
B: It hasn't got a handle?
A: Well, err, its red on one side and red at the back and the front and call – It's called something like a crow hammer. Do you have it for making holes?
B: Hold on, is it a power tool?
A: Yes, yes?
B: Oh I think I have it. I think I know. A drill?
A: Yes a drill Thankyou (Player B exchanges card)

Transcript 3 detection of failure (Difrancesco and Pullvermuller, 2012)
A: Chair with umm a, a in front of it, it's right, it's in front of it
B: Sorry?
A: Chair with an apple. Oh, no, a cushion, in front of it, in front if it, under, underneath it
B: Underneath the chair? (B shows card with cushin on the floor in front of the chair)
A: No, no, that the front one, the one benea –beneath it (A shows card with cushion beneath the chair. Card mismatch. A and B take back the cards and next player begins a new round).

Transcript 4 detection of failure in understanding (Difrancesco and Pullvermuller, 2012)
A: Could I have one brown bottle please?
B:One brown bottle. I'm afraid I can't give you any brown bottles?
A: Ok, Player C would you have one brown bottle please
C: No, I'm afraid I haven't got one.
A: Oh, Plater D would you have one brown bottle please?
D: I'm afraid to sat it but I don't have it either.
A: Ok, somebody has the brown bottle with a label – I'll just do a general one then. One brown bottle with a white label on it.
B: Ah, I have that.

A: May I have it please? (Player B shows and exchanges card)

PROPOSALS

Transcript 5 accepting (Difrancesco and Pullvermuller, 2012)
A: Can you help me with umm, would you like to play umm. I've lost it
B: You can describe it, A.
A: long stick with two people and a hole and a stick with a hole on the
end of it. Umm. I can't see what else is there?
B: So maybe you could tell me what we could do with the stick?
A: Umm it's two sticks with a ball and long, a long stick and ball; and a
long, umm a ball that you hit?
B: So you hit a ball?
A: Yes, with the long stick
B: I think I know. Would you like me to play golf with you? (Player A offers card and B also shows card, which matches)
A: Oh, yes. (Player A takes both cards upon confirmation of match).

Transcript 6 rejecting (Difrancesco and Pullvermuller, 2012)
A: B, would you like to join me walking the dog tomorrow?
B: No, I think my dog just want to stay in-indoors
A: Ah, OK. Well then C would you like to join me walking the dog?

Transcript 7 unsuccessful (Difrancesco and Pullvermuller, 2012)
A: Umm, right, umm I have here a, hmm a, big long rope and attached to that I've got some err, climbing frame, climbing frame and I'd like to know would you like to please, the, the climbing frame, the, rope and me
B: So you're planning a climbing activity tomorrow and are asking if
I would like to join you climbing a wall? Yes?
A: Yes, yes that's right
B: I'm very happy to join in (shows card depicting the activity "climbing indoors")
A: Oh, no. (Shows card depicting the activity "abseiling down a building")

Appendix 10 Accessible invitation letter

Northern Lincolnshire and Goole NHS Foundation Trust

The University Of Sheffield.

Speech and Language Therapy
Northern Lincolnshire and Goole
NHS Foundation Trust
Cliff Gardens
DN15 7BH

Speech therapy research study (Pilot of ILAT)

You are being **invited** to take part in a research study to evaluate the use of a **group therapy** to help you find your words more easily.

We are letting you know as you have difficulty talking from '**aphasia**' after your **stroke**.

If you would like **more information** about the Speech and Language Therapy project please contact:

Nicola Crook on 01724 290043.

I will telephone you in**1-2 weeks** to check you received this information.

Thank you for reading about this study.

Northern Lincolnshire and Goole NHS
NHS Foundation Trust

The University Of Sheffield.

Participant Information Sheet 1

1. Study Title

Evaluating the efficiency and acceptability of methods of delivering evidence based **aphasia** intervention (**intensive language action therapy**) to patients in the UK within the **NHS**: a pilot trial.

2. **Invitation**

You are being invited to take part in a research study to evaluate the use of a **group therapy** to help you talk more easily more easily. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please **take time to read the following information** carefully and discuss it with friends, relatives and your speech and language therapist if you wish. **Ask us if there is anything that is not clear** or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

3. **What is the purpose of the Study?**

People with **aphasia** typically receive speech and language therapy. Research suggests that people with aphasia **achieve the most improvement when therapy is delivered intensively**. However intensively delivered therapy requires more therapist time than current NHS resources allow. Intensive Language Action Therapy (ILAT)

is a **group therapy** that is delivered intensively. This project investigates:

1. if it is possible to **evaluate ILAT compared to usual SLT care** using a randomised controlled trial design,

2. whether it is **possible to recruit people with aphasia** and **allocate** them to ILAT therapy groups,

3. whether it is possible to deliver ILAT using **SLT assistants and volunteers** within the NHS,

4. the most **acceptable assessments** to use to measure whether ILAT is effective.

4. **Why have I been chosen?**

You have been chosen because **you have aphasia** from your stroke and find it difficult to find the words you wish to say.

5. **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still **free to withdraw at any time and without giving a reason**. Deciding not to take part, or withdrawing from the project will not affect your rights to any health, or voluntary services.

6. **What will happen to me if I take part?**

If you decide to take part, a **research speech and language therapist will visit you at home or at the group that you attend**. The therapist will carry out **assessments** of your language and daily life activities. Part of the assessment will

include a **video recording of a conversation** between you and the therapist. This will be sent securely to the study team at Sheffield University for analysis. They will not know any personal information about you e.g. your name or contact details.

These tests may take up to two hours. The therapist may visit you twice to complete the tests.

A computer system will randomly allocate you to **either**

- your **usual speech therapy** care

or

- your **usual speech therapy** care **plus a course of intensive group therapy** (intensive language action therapy)

The allocation is **random** and cannot be influenced by your speech and language therapist or the research team. You have an **equal chance** of being allocated to each of the groups above.

If you are asked to attend the intensive group therapy you will be allocated to a **group with 4 other people** with aphasia. You will **attend** the course for **4 hours a day for 2 weeks on Monday to Friday**. This will be as soon as another group is available after you have been allocated to receive the group therapy.

The **researcher** will **visit** you **again approximately four months after you find out whether you are having group therapy or your usual care** to repeat language **assessments** to see if your talking has **improved**.

If a **friend** or **family member** is there when the researcher visits we will ask them what they think about your communication. We will also ask them about being a carer.

A researcher will also **visit** you to ask you what you **thought about being in the study** and **what the therapy was like** after you complete the assessments.

7. **What are the side effects of taking part?**

We **do not expect any side effects from taking part**. If the course of group therapy does not suit your needs, it may cause frustration. If this happens you may decide to stop attending.

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

Taking part may give you the opportunity to have **further therapy**. This may help you to **talk more easily**.

9. **How long** will I be taking part?

The therapy itself lasts for two weeks. However, you will be a part of the research for approximately **6 months so that we can carry out language assessments and interviews**

10. What if something goes **wrong**?

If you wish to **complain** about any aspect of the way you have been approached or treated in this study, you can use the **National Health Service complaints** mechanisms. This will not affect the services you receive in any way. If you have any complaints or concerns, please **contact** the study manager, **Nicola Crook** 01724 290043.

Alternatively, you can use Sheffield University complaints procedure and contact the following person:

[Name], 'Registrar and Secretary' of the University of Sheffield, by post (Registrar and Secretary's Office, Firth Court, Western Bank, Sheffield, S10 2TN)

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

No publications or other public **information** will **identify you personally**.

12. What will happen to the **results** of the research study?

The results of this research study will be **published** in scientific journals and will be **presented** to stroke survivors and professionals after the end of the study (in about 3 years).

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

The research is organised by the University of Sheffield and funded by the Department of Health (National Institute for Health Research Health Doctoral Fellowship Programme). The sponsors of this study will pay Northern Lincolnshire and Goole HNS Foundation Trust for including you in this study.

14. Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favorable opinion by _____Research Ethics Committee.

Contact for further Information

If you have any questions regarding this study, please contact the **Nicola Crook**

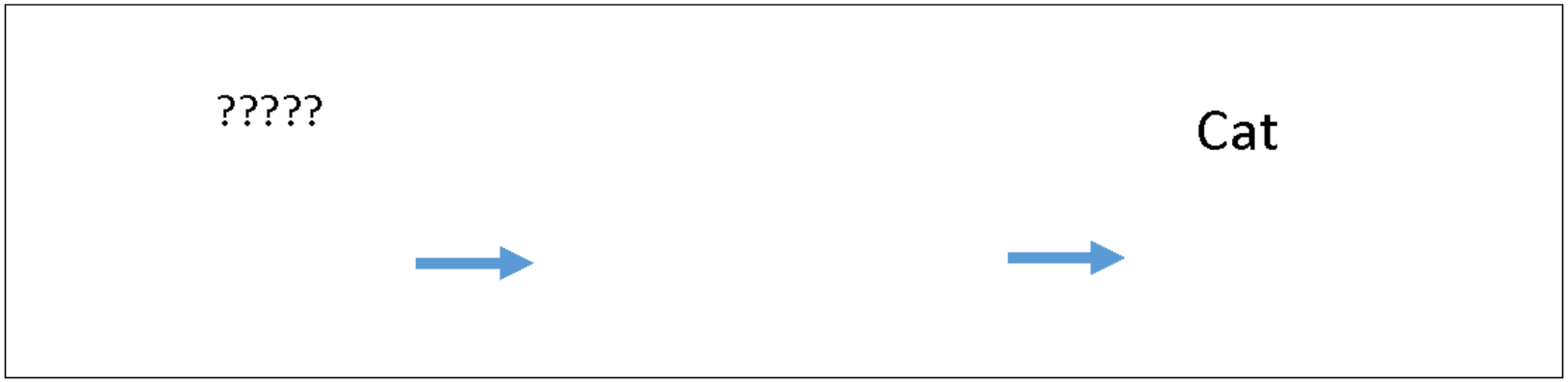
Thank you for reading about this study.

PATIENT INFORMATION SHEET 2 (PIS2)

Pilot of Intensive Language Action Therapy

Version 1.1 12/10/2016 IRAS ID: 210164

Intensive group therapy for aphasia



Investigation

Into

Intensive group therapy

For

People with aphasia ?????

Title

Evaluating the **delivery** of

aphasia intervention
(**intensive** language action therapy)

compared to usual care

within the **NHS**.

Invitation

You are being invited to take part in a **research study**

to evaluate the use of a **group therapy**

?????

Cat

to help you **talk more easily**.

- Please **take time** to **read** the following **information.**
- **Discuss it** with your **friends** and **relatives**.
- **Ask** us if there is anything this **not clear**
- or if you would like **more information**

++

- Take **time to decide** whether you wish to take part.

What is the **study about**?

- People with **aphasia**
- receive **speech and language therapy**.

?????

- People with aphasia **improve the most when therapy is delivered more often**.

- This requires **more therapist time**

++

- Which is **difficult** for the **NHS**

- Intensive Language Action Therapy (ILAT) is a **group therapy**

- that is delivered **intensively**,

- to **help** you to **talk more easily**.

We want to know:

- If it is possible to **compare intensive group therapy** (ILAT) **to usual therapy**

- If people with aphasia **want to take part**
- If **speech therapy assistants or volunteers** can deliver the intensive group therapy

- What is the best way to **measure** if people with aphasia are talking more easily

????? - - - - - - ?? - - - - - ?? - - - - Cat

- What people with aphasia **think** about the intensive group therapy (ILAT)

Why have I been chosen?

- You have **aphasia** from your **stroke**
- and find it **difficult to find the words** you want to say.

?????

Do I have to take part?

- No. It is **up to you** to decide whether or not to take part.

- If you decide to take part you will be given this **information sheet**.

- You will be asked to **sign a consent form.**

- If you decide to take part you are free to **withdraw** at any time.

- You **do not** need to give a **reason.**

- Not taking part or withdrawing from the project **will not** affect your **rights** to any **health, or voluntary services.**

- The consent form asks whether you agree to be contacted about **future research.**

- It is **up to you** to decide.

- You can **still take part** in **this project.**

What will happen to me if I take part?

- A research **speech and language therapist** will **visit** you at **home.**

- The therapist will carry out **assessments** of your **language.**

- This will include a **video recording** of a short **conversation.**

- The assessment may take **up to two hours.**

+

- The therapist may visit your house **twice** to complete these assessments.

1 hour + 1 hour

A **computer system** will randomly allocate you to **either**:

- **Normal therapy**

OR

- **Intensive group therapy**

- You have an **equal chance** of being in either group.

If you are asked to do the intensive group **therapy** you will:

- Be put in a **group of 4 people** with aphasia

- You will come to the group **5 days a week**

- For **2 weeks** **+**

- You will start the course as **soon** as a group is **available**.

Whichever group you are in the **researcher** will **visit** you again to repeat

language assessments to see if you **talking** has **improved.**

?????

\- - - - - - ?? - - - - - ?? - - - - - ?? - - - - - Cat

Your **friend or family member** will be asked what they think about your communication and about being a carer.

We would **like you to tell us what you think** about the project and the intensive group therapy.

The researcher will **visit** you at home to ask you some **questions**.

This interview will be **video recorded**.

What are the side effects of taking part?
We **do not expect any side effects from taking part**.

- If the course of group therapy does not suit your needs, it may cause **frustration**.

- If this happens you may **choose** to **stop** attending.

What are the possible benefits of taking part?

Taking part may give you the opportunity to have **further therapy**.

This may help you to **talk more easily**.

How long will you be taking part?

- The therapy lasts for **2 weeks** **+**

You will take part for
approximately 6 months
So we can do the assessments

What if **something goes wrong**?

If you wish to **complain**, you can use the **National Health Service complaints** process.

This will **not affect** the **services** you receive in any way.

You can **contact** the study manager, **Nicola Crook** 01724 290043.

Or you can use Sheffield University complaints procedure and contact the following person:
[Name], 'Registrar and Secretary' of the University of Sheffield, by post (Registrar and Secretary's Office, Firth Court, Western Bank, Sheffield, S10 2TN)

Will my taking part in this study be kept confidential?

No publications or other public **information** will **identify you personally**.

John Smith → A21C

Only **authorised** people will be **allowed** to see your **information**.

What will happen to the results of the research?

The results of this research study
will be **published** in scientific journals

and will be **presented** to stroke survivors and
professionals after the end of the study
(in about 3 years).

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

The research is organised by the **University of Sheffield**

and funded by the **Department of Health** (National Institute for Health Research Health Doctoral Fellowship Programme).

The sponsors of this study will pay Northern Lincolnshire and Goole HNS Foundation Trust for including you in this study.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a **Research Ethics Committee**, to protect your interests. This study has been reviewed and given favorable opinion by [Name] Research Ethics Committee.

Contact for further information

Researcher: Nicola Crook

Telephone: 01724 290043

Email: nkcrook1@sheffield.ac.uk

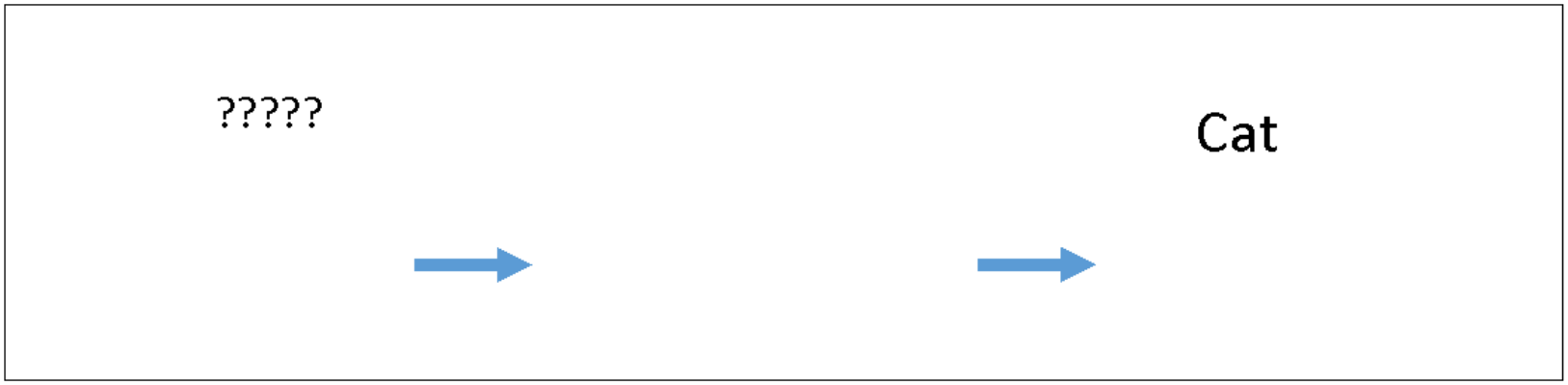
Thank you for reading about this study.

PATIENT INFORMATION SHEET 4 (PIS4)

Pilot of Intensive Language Action Therapy

Version 1.1 12/10/2016 IRAS ID: 210164

Intensive group therapy for aphasia



Intensive group therapy for aphasia

[video clip of ILAT]

What?

Group therapy

5 days a week

2 weeks

+

What?

OR

Normal therapy

Where?

At the Hospital

How long?

6 months

Can you talk better?

[video clip of assessments]

Would you like to be involved?

Appendix 14 Accessible consent form

Participant Identification Number for this trial:

Evaluating the efficiency and acceptability of methods of delivering evidence based aphasia intervention (**intensive language action therapy**) to patients in the UK **within the NHS**: a pilot trial.

PARTICIPANT CONSENT FORM

Please initial each box

	1. I confirm that I have **read** and **understand** the information sheet dated [date] (version [number]) for the above study. I have had the **opportunity** to ask **questions**. I have had these **answered** satisfactorily.
	2. I understand that my participation is **voluntary** and that I am free to **withdraw** at any time without giving any reason and without my medical care or legal rights being affected.
	3. I agree to short conversations being **video** recorded for the research study.
	4. I give **permission** for individuals from: • · **regulatory authorities**, • · the **NHS trust** • · researchers at the University of Sheffield to look at my **data collected during this study** and **medical notes** where it is relevant to the study.

	5. I **agree** to be **contacted** about **future research**.	
	6. I **agree** to **anonymised data** about me being used in **future research**.	
	7. I **agree** to take part in the above study.	

PARTICIPANT CONSENT FORM (Page 2)

Participant Identification Number for this trial:

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	
Name of Person taking consent	Date	Signature
_____	_____	_____
Name of Witness (if applicable)	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Appendix 15 Consultee declaration

CONSULTEE DECLARATION FORM

Participant Identification Number for this trial:
Consultee Initials:
Name of Researcher: Nicola Crook

Evaluating the efficiency and acceptability of methods of delivering evidence based aphasia intervention (intensive language action therapy) to patients in the UK within the NHS: a pilot trial.

Please initial each box

1. I [name of consultee] have been consulted about [name of potential participant]'s

participation in this research project. I have had the opportunity to ask questions about the study.

2. I understand the purpose of the study and know what my relative's/friend's involvement will be.

3. In my opinion, he/she would have no objection to taking part in the above study.

4. I understand that relevant sections of his/her care record and data collected during the studymay be looked at by responsible individuals from the University of Sheffield and Northern Lincolnshire and Goole NHS Foundation Trust or from regulatory authorities, where it is relevant to their taking part in this research.

4. I understand that my relative's/friend's participation is voluntary and that I can and request he/she is withdrawn from the study at any time, without giving any

reason without his/her care or legal rights being affected.

4. In my opinion, my relative/friend would have no objection to having a short conversation being video recorded for the study.

5. In my opinion, he/she would have no objection to be contacted about other research in the future.

6 In my opinion, he/she would have no objection to anonymised data about my relative/friend
being used in future research.

Name of relative/friend (participant): _____

_____ _____
_____
Name of Consultee Date Signature

_____ _____
_____
Name of Person Date Signature
taking consent

Relationship to participant:
_____

When completed: 1 for consultee; 1 for researcher site file; 1 (original) to be kept in medical notes.

Appendix 16 Carer information sheet

Carer Information Sheet

Study title
Evaluating the efficiency and acceptability of methods of delivering evidence based aphasia intervention (intensive language action therapy) to patients in the UK within the NHS: a pilot trial.

Invitation
You are invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?
People with aphasia typically receive speech and language therapy. Research suggests that people with aphasia achieve the most improvement when therapy is delivered intensively. However intensively delivered therapy requires more therapist time than current NHS resources allow. Intensive Language Action Therapy (ILAT) is a group therapy that is delivered intensively. This project investigates:

5. if it is possible to evaluate ILAT compared to usual SLT care using a randomised controlled trial design,

6. whether it is possible to recruit people with aphasia and allocate them to ILAT therapy groups,

7. whether it is possible to deliver ILAT using SLT assistants and volunteers within the NHS,

8. the most acceptable assessments to use to measure whether ILAT is effective.

Why have I been chosen?
You have been chosen because your relative/friend has aphasia and has agreed to take part in the study.

Do I have to take part?
It is up to you to decide whether or not to take part. It you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the project will not affect your rights or your relatives/friends rights to any health, or voluntary services. Your decision will not affect your relative's/friend's involvement in the study.

What will happen to me if I take part?
If you decide to take part, a research speech and language therapist will carry out assessments of your perception of your relative's/friend's language ability and its effect on the daily life of both your relative/friend and yourself. You will also complete some assessments that examine what it is like to be a carer and your quality of life. The assessment carried out with you may take up to thirty minutes. The therapist will conduct these assessments during the visits to your relative/friend at home.

A computer system will randomly allocate your relative/friend to either

- their usual speech therapy care

or

- their usual speech therapy care plus a course of intensive group therapy (intensive language action therapy)

The allocation is random and cannot be influenced by your relative's/friend's speech and language therapist or the research team. Your relative/friend has an equal chance of being allocated to each of the groups above.

The researcher will visit you again once more to repeat the assessments with you. We would like to repeat the assessment whether your relative/friend receives the group therapy or not.

What is Intensive Language Action Therapy?
The therapy being tested in Intensive Language Action Therapy (ILAT). ILAT is a group therapy that is delivered intensely. If your relative/friend is allocated to the intensive group therapy they will be assigned to a group of 4 people to receive a course of ILAT. Your relative/friend will attend the course of ILAT 4 hours a day for 2 weeks on Monday to Friday.

What are the side effects of taking part?
We do not expect any side effects for carers participating in the assessments. If however you find any of the questions distressing, you do not have to answer them.

What are the possible benefits of taking part?
Taking part in the assessment process of the research may not have any direct benefits for you. However, the information you provide will help the speech and language therapy profession to understand the impact of aphasia and aphasia treatment on carers of people with aphasia.

What if something goes wrong?
If you wish to complain about any aspect of the way you have been approached or treated in this study, you can use the National Health Service complaints mechanisms. This will not affect the services you receive in any way. If you have any complaints or concerns, please contact the study manager, Nicola Crook on telephone 01724 290043.
Alternatively, you can use Sheffield University complaints procedure and contact the following person: Dr *[Name], 'Registrar and Secretary' of the University of Sheffield, by post (Registrar and Secretary's Office, Firth Court, Western Bank, Sheffield, S10 2TN)*

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be **anonymised** by a computer coding system.

What will happen to the results of the research study?
The results of this research study will be published in scientific journals and will be presented to stroke survivors and professionals after the end of the study.

Who is organising and funding the research?
The research is organised by the University of Sheffield and funded by the Department of Health (National Institute of Health Research Doctoral Fellowship Programme). The sponsors of this study will pay Northern Lincolnshire and Goole NHS Foundation Trust for including you in this study.

Contact for further information
If you have questions regarding this study, please contact Nicola Crook on telephone 01724 290043.

Appendix 17 Carer consent form

CARER CONSENT FORM

Participant Identification Number for this trial:
Carer Initials:
Name of Researcher: Nicola Crook

Evaluating the efficiency and acceptability of methods of delivering evidence based aphasia intervention (intensive language action therapy) to patients in the UK within the NHS: a pilot trial.

Please initial each box

1. I confirm that I have read and understand the information sheet dated [date] (version [number]) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand the purpose of the study and know what my involvement will be.

3. I understand I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected.

4. I agree to be contacted about other research in the future.

5. I agree to anonymised data about me being used in future research.

6. I agree to take part in the above study.

Name of relative/friend (participant): _____

_____	_____	_____
Name of Consultee	Date	Signature

_____	_____	_____
Name of Person taking consent	Date	Signature

Relationship to participant: _____
When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Appendix 18 Therapy Assistant/volunteer information sheet

Speech and Language Therapy Assistant/Volunteer Information Sheet

Evaluating the efficiency and acceptability of methods of delivering evidence based aphasia intervention (intensive language action therapy) to patients in the UK within the NHS: a pilot trial.

You are invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?
People with aphasia typically receive speech and language therapy. Research suggests that people with aphasia achieve the most improvement when therapy is delivered intensively. However intensively delivered therapy requires more therapist time than current NHS resources allow. Intensive Language Action Therapy (ILAT) is a group therapy that is delivered intensively. This project investigates:

1. if it is possible to evaluate ILAT compared to usual SLT care using a randomised controlled trial design,

2. whether it is possible to recruit people with aphasia and allocate them to ILAT therapy groups,

3. whether it is possible to deliver ILAT using SLT assistants and volunteers within the NHS,

the most acceptable assessments to use to measure whether ILAT is effective.

Why have I been chosen?
You have been chosen because you are a speech and language therapy assistant or volunteer or would like to be a volunteer involved in this research as a facilitator of ILAT.

Do I have to take part?
It is up to you to decide whether or not to take part. It you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part, or withdrawing from the project will not affect your rights to any health, or voluntary services.

What will happen to me if I take part?
If you decide to take part, you will receive training to facilitate ILAT, you will be observed delivering ILAT and complete an interview with an outcome measures therapist exploring the acceptability of the methods used to deliver ILAT within the trial.

What is Intensive Language Action Therapy?
The therapy being tested in Intensive Language Action Therapy (ILAT). ILAT is a group therapy that is delivered intensely. The participants will be assigned to a group of 4 people to receive a course of ILAT and will attend the course of ILAT 4 hours a day for 2 weeks on Monday to Friday.

What are the side effects of taking part?
We do not expect any side effects for SLTA/volunteers participating in the interviews. If, however, you find any of the questions distressing, you do not have to answer them.

What are the possible benefits of taking part?
Taking part in the interview process of the research may not have any direct benefits for you. However, the information you provide will help the researcher identify any barriers or facilitators and explore the acceptability of SLTA/volunteers delivering ILAT.

What if something goes wrong?
If you wish to complain about any aspect of the way you have been approached or treated in this study, you can use the National Health Service complaints mechanisms. This will not affect the services you receive in any way. If you have any complaints or concerns, please contact the study manager, Nicola Crook on telephone 01724 290043.

Alternatively, you can use Sheffield University complaints procedure and contact the following person: Dr *[Name], 'Registrar and Secretary' of the University of Sheffield, by post (Registrar and Secretary's Office, Firth Court, Western Bank, Sheffield, S10 2TN)*

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be **anonymised** by a computer coding system.

What will happen to the results of the research study?
The results of this research study will be published in scientific journals and will be presented to stroke survivors and professionals after the end of the study.

Who is organising and funding the research?
The research is organised by the University of Sheffield and funded by the Department of Health (National Institute of Health Research Doctoral Fellowship Programme). The sponsors of this study will pay Northern Lincolnshire and Goole NHS Foundation Trust for including you in this study.

Contact for further information
If you have questions regarding this study, please contact Nicola Crook on telephone 01724 290043.

Appendix 19 Therapy Assistant/volunteer consent form

SPEECH & LANGUAGE THERAPY ASSISTANT/VOLUNTEER CONSENT FORM

Participant Identification Number for this trial:

Evaluating the efficiency and acceptability of methods of delivering evidence based aphasia intervention (intensive language action therapy) to patients in the UK within the NHS: a pilot trial.

Name of Researcher: Nicola Crook

Please initial each box

1. I confirm that I have read and understand the information sheet dated [date] (version [number]) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

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

4. I agree to be contacted about other research in the future.

5. I agree to anonymised data about me being used in future research.

6. I agree to take part in the above study.

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Appendix 20 Volunteer person specification and role description

Appendix 21 Therapy Outcome Measure Activity and Impairment Scales and rater instructions

Procedure for TOMS rating

You will receive videos in pairs e.g. A and B (both of the same participant)

1. Use a timer to watch only the first 10 minutes of video **A** of an AB pair and score according to activity scale of the TOMs for Aphasia

- Start at the top or bottom of the TOMs scale based on your first impression of whether it is good/poor and work up or down through the descriptors.
- Remember that you can select a score half way between two of the written descriptors (scoring .5)
- Focus on the underlined part of the descriptors as these can be judged through watching a video

2. Use a timer to watch only the first 10 minutes of video **B** of an AB pair and score according to activity scale of the TOMs for Aphasia

- Start at the top or bottom of the TOMs scale based on your first impression of whether it is good/poor and work up or down through the descriptors.

- Remember that you can select a score half way between two of the written descriptors (scoring .5)
- Focus on the underlined part of the descriptors as these can be judged through watching a video

3. Check you are happy with the scores you have allocated for both videos. Modify if needed to ensure that if one video seemed better than the other, that the scores reflect this (NB this is likely to be a small change to the score only)

4. Document the final scores for A and B before moving on to the next pair of videos

Prompting/cueing includes:

- Therapist checking what the patient meant if it was ambiguous
- Therapist giving cues (e.g. semantic or phonemic)
- Therapist providing lead in phrases

NOT summarising/recapping what has been said in the conversation

TOMS Activity scale for aphasia

1. Unable to communicate in any way. No effective communication. No interaction.

2. Occasionally able to make basic needs known with familiar persons or trained listener in familiar contexts. Minimal communication with maximal assistance.

3. Limited functional communication. Consistently able to make basic needs/conversation understood but is heavily dependent on cues and context. Communicates better with trained listener or family members or in familiar settings. Frequent repetition required. Maintains meaningful interaction related to here and now.

4. Consistently able to make needs known but can sometimes convey more information than this. Some inconsistency in unfamiliar settings. Is less dependent for intelligibility on cues and context. Occasional repetition required. Communicates beyond here/now with familiar persons; needs cues and prompting.

5. Can be understood most of the time by any listener despite communication irregularities. Holds conversation; requires occasional prompts, particularly with a wider range of people.

6. Communicates effectively in all situations

TOMS Impairment scale for aphasia

1. **Aphasia affecting all modalities:** Auditory and reading comprehension inconsistent even at one keyword. No meaningful expression.

2. **Severe aphasia:** Auditory and/or reading comprehension is consistent at one keyword level. Occasionally understand and express limited amount.

3. **Severe/moderate aphasia:** Auditory and/or reading comprehension is consistent at a minimum of two or three keyword level. Some limited verbal and/or written expression used appropriately and purposefully.

4. **Moderate aphasia:** Constant auditory and/or reading comprehension for simple sentences or structures. Inconsistent with complex commands and structures. Consistently reduced verbal and/or written language structure and vocabulary. May have a specific more severe difficulty or modality.

5. **Mild aphasia:** Occasional difficulties present in auditory and/or reading comprehension and in vernal and/or written expression.

6. **No aphasia**

Appendix 22 Data Management Plan

Data Management Plan

Key study documents

CRFs and sign off forms	X:\ScHARR\PR_ILAT_Pilot\Data_Management\CRF
Database specification	X:\ScHARR\PR_ILAT_Pilot\Data_Management\Database\Set-up\Approval (v1; living document stored on Google Drive)
Protocol	X:\ScHARR\PR_ILAT_Pilot\Data_Management\Study documents\Protocol

Study timelines (approximate)

FPFV (recruitment starts)	November/December 2016
LPFV (recruitment complete)	December 2017
LPLV (follow up complete)	April 2018
Database Freeze	May 2018
Database Lock	June 2018

Data management timelines are documented within the timelines tab of the database spec. The project plan Gantt chart is stored in the Trial Master File (TMF).

Case report form development

Case report forms (CRF) used for collecting participant level data are developed in line with DM003 and approved in line with DM013.

Study database development

The study database is developed in line with DM004. Full details of the database structure are contained within the database specification document.

Database access, support and training
Once the study database is live, the data manager will give the study manger access to manage the study users. The study manager will then be responsible for adding users, although this task may be delegated. Before adding users (or requesting that they be added), the study manager should check that the individuals concerned are authorised to perform their given role.

Outcome measures therapists will enter the four-month outcome data. They should be kept blind to the allocation so should not see the randomisation form or the intervention log, or any of the baseline forms.

Users should only be given permissions they require to perform their role. The system provides the opportunity to control which sites each user can access, whether users are able to view/enter data (and for which forms), and which users can view discrepancies, export data and access each of the study reports.

The central data management team may need access to trouble shoot or provide advice.

The study database resides on Prospect, a system designed to be user friendly in order to minimise the need for training and supporting users. However, users may contact the central study team / data management team by email or telephone if they require support, and a feedback form is built into the system to allow them to notify the developers and data managers of any issues. Additionally, ad-hoc or formal training can be provided if deemed necessary, either face-to-face or remotely. Also, a generic user guide is available.

Data collection and entry
Potential participants may be identified through three routes:

1. Identification by speech and language therapists (SLTs) from their caseloads
2. Via the Stroke Association Communication Support Group
3. Via Big CACTUS: participants from Northern Lincolnshire & Goole NHS Foundation Trust who indicated a willingness to take part in future research

Candidates identified by the above methods will be contacted to see if they are interested in the trial and, if so, assessed for eligibility prior to consent being taken and baseline data collected at a home visit by the study manager prior to entry on the study database.

Following the baseline assessment participants will be randomised. Those in the intervention arm will receive a two-week course of Intensive Language Action Therapy delivered by speech and language therapy assistants and/or volunteers. An intervention log will be completed with information about participants' progress. Once completed these forms will be sent to the study manager to be entered in to the study database.

At four months, an outcome measures therapist will arrange a follow-up home visit and collect the outcome data and enter it on the database.

Adverse events will be collected (and, if serious, reported) throughout the study.

Data entry can begin as soon as the database is live and the first patient is screened. Data entry will continue throughout the study.

Data validation

Point of entry validation

This is enforced by checks carried out during data entry in order to ensure mandatory fields are completed and to prevent entry of invalid data. These are defined on the fields tab of the database specification (min, max and validation columns).

Post-entry validation

This is the checking of data which has already been entered based on a set of pre-defined rules. The discrepancies generated will need to be reviewed and appropriately concluded on an ongoing basis.

Validation rules

The data manager will draw up a list of validation rules to identify potentially invalid, out-of-range, inconsistent or missing data; and to identify potential protocol non compliances. Other study team members (e.g. the statistician and study manager) may help identify these rules.

Version 1 of these rules will be documented in the Data Validation Specification (DVS). The DVS will be reviewed and approved by the study manager and statistician before post-entry validation begins.

Subsequent additions/revisions will be logged, documenting what has changed, when and why.

Discrepancy generation

Where data is not compliant with the validation rules, discrepancies will be generated and reported via Prospect. These reports will be available to applicable staff for resolution (only staff with permissions for the form or the validation tool overall will see the discrepancies from that form). The data manager (or designee) will produce these data discrepancy reports, usually on a weekly basis and as required.

Discrepancy resolution

The applicable staff should investigate all issues and either correct or confirm the data on an ongoing basis.

Where updates are made to participant data on the study database, the original pCRF should also be updated (where applicable).

Discrepancies will be managed within Prospect in order to provide a robust system for keeping track of discrepancies.

Ad-hoc validation

Anyone (e.g. the TMG, TSC, data manager, trial manager, statistician etc.) may identify data quality issues either as a result of reviewing status reports or other data. Rules should be defined to cover these issues. Where possible these rules should be managed within Prospect, but if this is not practicable it is still important to document and track them.

Data reconciliation

In cases where the data are stored in more than one place (e.g. randomisation data in SCRAM and Prospect) checks will be carried out to ensure the data matches. This will be carried out at database freeze. Appropriate action will be taken and documented as part of the reconciliation process.

Self-evident corrections (SECs)

Some data changes are self-evident and can be made by central staff. The self-evident corrections are documented within the study database specification. As the study progresses issues may become apparent which can be addressed by supplementing the list of SECs.

The chief investigator should approve the list, and any subsequent additions or amendments.
If a SEC is used as the reason for a data edit, reason for change of 'self-evident correction' should be used and the SEC number specified. If a SEC is applied at the data entry stage (by central staff entering participant questionnaires, for example), a field annotation should be created with the SEC number as the annotation. In both cases only the database needs to be updated, not the pCRF (if applicable).

At the end of the study the CI should be provided with details of the actual changes made to data as a result of applying SECs. This will be produced via the self-evident correction listing report in Prospect and by filtering the data export of the field annotations.

Verification of data entry
This is the process of checking that the data entered on the database matches the pCRF by having a second person independently re-enter the pCRF data, identifying any discrepancies between the database and the pCRF. Verification can be useful to identify systematic errors with a particular site, data entry person or field.

A sample of agreed forms will be verified by a member of the central data management team and any issues will be logged. The central study team will review the issues and document any follow up actions.

Status reporting
The study manager will be responsible for producing reports for study meetings. The data manager will provide support in producing these where required.

CTRU data storage, access and archiving
Physical data
No paper forms will be stored at CTRU. They will be stored, processed and archived at site in line with site policies.

Electronic data
Electronic data are stored on a secure, backed-up database based in the University computing department (CICS). Access to the trial data is managed within Prospect using advanced permissions associated with usernames and passwords; site staff have access only to participants recruited at their site. Prospect maintains a full audit trail of all modifications to the data.

Electronic data will be retained for a minimum of 5 years following completion.

Study database lock
As detailed in DM012.

Data format for statistical analysis
The data manager will provide the study manager and statistician with CSV download(s) containing the study data at database freeze and lock.

Critical items
The critical items are those that inform the calculation of the primary outcomes:
- Recruitment and identification information
- Intervention compliance and withdrawal information
- Delay between randomisation and group assignment and intervention start
- Time between intervention and follow-up outcome measures completion

- Timeliness of four-month outcome measures completion
- Sufficient completion of outcome measures (i.e. to allow calculation of scores)

Approval

Name	Role	Signature	Date
Tim Chater	Data manager	_____	_____
Nicola Crook	Study manager	_____	_____
Laura Mandefield	Statistician	_____	_____

Appendix 23 Statistical Analysis Plan

Study title: ILAT Pilot
Evaluating the efficiency and acceptability of methods of delivering evidence based aphasia intervention (intensive language action therapy) to patients in the UK within the NHS: a pilot trial.

NIHR CATDoc 01042016

Statistical Analysis Plan Version 1

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Contents

List of abbreviations used

AE	Adverse Event
ILAT	Intensive Language Action Therapy
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CTRU	Sheffield Clinical Trials Research Unit
DMEC	Data Monitoring and Ethics Committee
ICC	Intra Cluster Correlation
ITT	Intention to Treat
MI	Multiple Imputation
NSAE	Non-Serious Adverse Event
PSD	Post Stroke Depression
SOP	Standard Operating Procedure

SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
TMG	Trial Management Group
TSC	Trial Steering Committee

Introduction

This statistical analysis plan (SAP) is written in conjunction with the International Conference on Harmonisation topic E9 [1], applicable standard operating procedures from the University of Sheffield Clinical Trials Research Unit (CTRU) and trial documents (Protocol, case report form (CRF) and Data Validation Specifications). The SAP will guide the Trial Statistician during the statistical analysis of all quantitative outcomes in order to answer the objectives of the study.

Study Background

This study is a pragmatic, parallel group randomised controlled pilot trial comparing Intensive Language Action Therapy (ILAT) facilitated by Speech and Language Therapy assistants/volunteers with usual care. An embedded qualitative study will allow a triangulation mixed methods approach to explore the perceptions, acceptability and experience of ILAT to the participants and service providers (Assistants/volunteers). Semi-structured interviews will explore facilitators and barriers to success during ILAT. Pragmatism as a world view will allow the research to examine the research questions from different angles focusing on actions, situations and consequences that affect the success of ILAT (Creswell, 2014). This study is funded by the National Institute for Health Research (NIHR) CATdoc Fellowship. All statistical analyses will be performed in a validated statistical software package such as R [2].

Objectives & Outcomes

This pilot trial aims to test the methodology for evaluating the impact of ILAT for patients, carers and the NHS to inform a future large, multi-centre trial. The research will examine the feasibility and acceptability of using volunteers and therapy assistants to facilitate ILAT. This proposal outlines a mixed method pilot study in line with the 'feasibility' and 'pilot' stages of evaluation within the MRC framework for Developing and evaluating Complex Interventions to Improve Health (2008).

Study aims

1. To examine the feasibility of undertaking a randomised control trial to compare the clinical effectiveness of ILAT facilitated by trained assistants/laypersons with usual treatment.

Objectives

- Recruitment rates will be estimated.
- The most appropriate and acceptable outcome measures to evaluate whether the goal of the ILAT intervention is achieved will be assessed.
- The completion rates and acceptability of selected outcome measures will be estimated.
- The feasibility of the randomisation process exploring any delays/difficulties in delivering group therapy in a timely way following randomisation will be assessed.
- The feasibility of delivering ILAT using assistants/ volunteers will be assessed.

2. To evaluate the acceptability of ILAT delivered by trained assistants/volunteers using interviews with participants, SLT's, assistants and laypersons.

Semi-structured interviews will be completed for participants and service providers (assistants/volunteers) to explore acceptability of ILAT. Interviews will also explore facilitators and barriers to success during ILAT. This data will be compared with the quantitative improvement shown from outcome measure assessment data allowing triangulation to more fully examine and explain the results.

Aim one of this study is to examine the feasibility of undertaking a randomised control trial to compare the clinical effectiveness of ILAT facilitated by trained assistants/laypersons with usual care.

Therefore, outcomes for aim one are;

a. Feasibility of recruitment to the main trial – number of participants recruited per month and in a 16-month period

b. Acceptability of the research procedures – as described by participants through interviews

c. Feasibility of randomisation and allocation to treatment arm (ILAT) through the description of how groups were formed, the time taken to form groups and the number of four-month outcome measures completed in within one month of the 4 month post randomisation time point.

d. Appropriateness and acceptability of the clinical outcome measures for assessing the impact of ILAT - the extent to which the clinical outcome measure assessments measure the intended outcome of the intervention, and the acceptability to the participants indicated by completion rates and interview data.

The outcomes for aim two examine the feasibility of delivering ILAT using assistants and volunteers based on the following;

a. Acceptability of ILAT to participants, assistants and volunteers – as described by participants through qualitative interviews

b. Feasibility of delivering ILAT by assistants and volunteers under the supervision of an experienced SLT through piloting the training and manualized procedures for the delivery of ILAT, examining the burden of supervision for the research SLT including the total number of hours and the number of supervision sessions required per ILAT course.

c. Treatment fidelity of ILAT – through the observation/video recording and analysis of a sample of treatment sessions,

d. Facilitators and barriers to ILAT success – as described by participants through qualitative interviews

Clinical Outcomes

The primary clinical outcome measure at 4-months is conversational ability rated through video recorded conversations using Therapy Outcome Measures (Enderby, John & Petheram, 2006) Activity scale following the procedure described by Hesketh et al (2008). Conversational ability will also be rated using the Impairment Scale of the TOMs.

The following secondary clinical outcomes have also been selected to further examine the clinical impact of ILAT;

- Naming ability and sentence production will be measured using the Comprehensive Aphasia Test Subtests: Naming objects and picture description (Swinburn, Porter & Howard, 2004)
- Participant rated perceptions of communication ability will be measured using the Communication Outcome After Stroke (patient rated outcome measure) (Long et al, 2008)
- Carers perceptions of participant communication ability will be measured using the Carer Communication Outcome After Stroke (carer rating of participant communication) (Long et al, 2008).

- Health related quality of life will be measured using the EQ-5D-5L aphasia friendly version and proxy rated EQ-5D-5L (Janssen et al, 2015).
- Carer health related quality of life will be measured using the Carer QoL (Brouwer et al, 2006).

The EQ5D and Carer QoL are included in this trial to allow the complete trialing of the burden of completion for the full package of measures that would be needed for health economic evaluation in the full trial.

Sample Size Estimation

The primary objectives of the pilot study are to assess the feasibility of undertaking the trial. The study will aim to recruit 12 evaluable patients per arm. This sample size is not based on any formal power considerations but will be sufficient to estimate the parameters for the design of a future trial (Julious, 2005) The trial will therefore aim to recruit 32 participants in total to allow for potential dropout within the time period of 16 months. Effect size for the full trial will not be calculated as the sample size is too small to provide reliable estimates. Instead future sample size calculation will be based on published data from trials using similar populations and similar clinical outcome measures (Palmer, et al, 2015).

Randomisation & Blinding

Patients will be randomised at baseline (after consent and baseline assessment) in a 1:1 ratio to Intensive Language Action Therapy (ILAT) or usual care. Randomisation will be stratified by time post stroke (<1 year, 1-5 years, >5 years) and severity of aphasia (mild, moderate and severe) and will be conducted using a computer generated pseudo-random list with random permuted blocks of varying sizes, created and hosted by the Sheffield CTRU.

Participants will be randomised after consent and baseline assessment. The research SLT will complete the baseline assessments prior to randomisation. It is impossible to blind any of the participants, assistants or volunteers to the intervention provided. However, trained assessors will complete the four mouth outcome measures blind to group allocation and will have had no involvement in recruitment or intervention. Blinding may be broken through patient conversation, therefore assessors will be asked to record whether they think the trial arm was revealed and how this was determined to assess the extent of unblinding. Analysis will be undertaken blind to treatment allocation as all assessment data will be provided to the research SLT anonymised.

Interim Analysis & Study Monitoring

This study has no planned interim analysis or early stopping. Two committees have been set up to govern the conduct of the study:

- Trial Steering Committee (TSC)
- Trial Management Group (TMG)

The TSC consists of an independent chair with clinical and research expertise in the topic area, and three other topic experts, as the sponsor sees fit and as agreed by the grant awarding body. The TSC will meet as necessary to supervise the overall conduct of the trial.

Decision to stop the trial early on grounds of safety will be made by the TMG, TSC and the Sponsor.

Data Sources, Evaluability & Study Populations

Data Sources

The data used in this study will come from data entered onto the CRFs and questionnaires completed and entered onto the CTRU's web-based data management system for the capture and storage of patient data.

Data Collection

Data will be collected from patients at the following points:

- Eligibility assessment;
- Baseline;

- 4 months post randomisation. For the purpose of the trial, data that is collected within the period 4 weeks before or after the 4 month time point will be accepted.

Follow up data may be collected in person. The number of patients who were assessed by each method will be reported by time points.

Table 1: A summary of data collection forms.

FORMS and OUTCOME MEASURES	Screening	Recruitment	Baseline	6 months
Reply slip	X			
Initial Screening Log	X			
Screening Log	X			
Receipt of Screening Measures	X			
Contact Details	X			
Pre consent information	X			
Eligibility		X		
Consent form		X		
Randomisation		X		
Demographics		X		
Stroke History		X		
Carer Consent		X		
Carer Details		X		
Adverse Events			*Ongoing*	
COAST Carer COAST			*X*	
CAT Naming			*X*	
CAT Picture description			X	
Care for communication			X	X
Therapy for communication			X	X
EQ5D5L- Aphasia friendly EQ5D5L (carer) EQ5D5L (proxy)			X	X
TOM's Activity and Impairment			X	X
Daily Intervention Log			*Ongoing*	
Intervention withdrawal			*Ongoing*	
Protocol non-compliance			*Ongoing*	
Study continuation/discontinuation (Patient)			*Ongoing*	
Study continuation/discontinuation (Carer)			*Ongoing*	

Protocol Non-compliances

For the purpose of this study, a non-compliance in the ILAT arm is based on attendance of therapy sessions. Primary analysis will be conducted on the intention to treat (ITT)

population (outlined in Section 5.5.1), however exploratory analysis may be conducted excluding patients who do not comply with protocol. Non-compliance will be assessed on a case by case basis, blinded to outcome based on level of attendance.

Study Population

The study population will be adult patients (18+) who have suffered a stroke and subsequently have been diagnosed with identified through past and current speech and language therapy (SLT) records by members of the clinical team at Northern Lincolnshire and Goole NHS Foundation Trust (NLaG), or through the Stroke Association communication support coordinator in North and North East Lincolnshire. Full inclusion and exclusion criteria can be found in the study protocol.

Analysis Population

Intention to Treat

The ITT population includes all patients for whom consent is obtained and who are randomised to treatment. This is the primary analysis set and endpoints will be summarised for the intention to treat population unless stated otherwise.

Statistical Analysis

General Considerations

This study is a pragmatic, parallel group randomised controlled pilot trial, data will be reported and presented according to the proposed modifications for reporting pilot trials as well as the CONSORT statement [14,15]. The analysis will be performed on an ITT basis. The final analysis will be performed after data lock by PhD student under the supervision of the Trial Statistician and PhD supervisors.

Recruitment and Attrition Rates

Levels of recruitment, consent and patient throughput will be reported and presented in the CONSORT flow diagram. An example of the CONSORT flow diagram can be seen in Section 10.1.

The following figures will be reported either in the CONSORT flow diagram or in a separate summary table:

The number of potential patients who:

- Are potentially eligible as identified by the study team at each participating centre;
- Were approached for the study;
- Were recruited per month;
- Completed each assessment at baseline and 4-months;
- Were randomised to treatment or control;
- Were withdrawn and lost to follow up by treatment group and overall;
- Discontinued ILAT and the reasons for discontinuation;
- Were included and excluded from analysis and the reasons for exclusion by treatment group and overall;
- Had missing outcome measures at baseline and/or 4 months by treatment group and overall;
- Deviated from protocol by treatment group and overall.

Reasons for Refused Consent

Reasons for refused consent, where given, will be recorded on the CRF. Statements on refusal of consent categorised as ‘other’ with details will be classified into categories where possible. The number and percentage of patients refusing consent for each category will be reported (as a proportion of all patients that refused consent) by centre and by randomised group.

Eligibility

Eligibility to participate will be assessed at the following points:

- Pre-screening- the research SLT at each centre will identify potential patients. The process for recruitment will vary depending on the specifics of where the participant is recruited from. These processes are outlined in the Study Protocol;
- Screening- eligibility assessment will be carried out (CAT naming);
- Consent and Baseline (0 weeks) – further eligibility assessment will be carried out;

The numbers and reasons for exclusion will be reported at each of these stages and overall.

Attrition

The rate of attrition will be reported (defined as the proportion of the consented and randomised participants who withdrew or were lost to follow up). The reasons for attrition, where provided, will be reported as number and percentage in category. Attrition will also be presented by treatment arm, site and time since stroke.

Number of Missing Values/Complete Cases

We will report the number of patients who had complete data for each of the key parameters (each outcome measure) for each time-point by treatment group and overall.

For patient and carer questionnaires, the item response rate at each visit (baseline and 4 months) will be reported. Response rate will be measured as a fraction of the total number of items. An example of this table can be seen in Section 10.2.

Baseline Characteristics

The baseline demographics and clinical characteristics of the patients will be reported. For the continuous variables (e.g. age) mean and SD will be presented or median and inter quartile range (IQR) depending on the distribution of the data. The number of observations used in each calculation will be presented alongside the summaries. Stroke characteristics will be reported. Stroke History which includes the date of the patient's most recent stroke will be recorded. For the categorical variables, (e.g. centre), the number and percentage of patients in each of the categories and the total number of observations will be presented.

All baseline summaries will be presented and reported for each treatment group and in total. An example of the table is given in Section 10.2. No statistical significance testing will be done to test baseline imbalances between the intervention arms but any noteworthy differences will be descriptively reported.

The following summaries will be presented:

Demographics:	Age, Sex, Ethnicity
Stroke characteristics:	Onset, Type, Location, Lateralisation
Patient reported: outcomes	EQ5D-5L, COAST, Carer COAST, Carerqol-7D

Intervention Adherence

ILAT will be reported as the number of sessions attended. There will be a maximum of 10 sessions offered. There will be no expected number of therapy sessions as this is expected to vary between patients. However, any scheduled therapy sessions that are missed will be recorded. The mean number of sessions attended and not attended for the ILAT group will be presented.

Intervention Fidelity

To ensure the fidelity of the intervention, the content of treatment will be described and analysed. This will be achieved by video recording intervention sessions. This will enable the checking of whether the treatment is being delivered according to the manual and the videos may be used for future training. The video recordings will be transferred to a secure encrypted device and deleted from the video recorder prior to transportation and stored in a secure area on the University of Sheffield server.

ILAT is a structured group therapy where participants play language action games to support improved spoken out put using words and sentences. The language action games are graded and shaped to ensure each participant in the course is communicating at their optimum. Assistants and/or volunteer laypersons will facilitate ILAT under the supervision of the researcher. Assistants and volunteer laypersons will complete a progress sheet for each participant to feedback to the research SLT to allow the monitoring and progression of each participant through the therapy. A selection of ILAT course sessions will be observed by the researcher to check for consistency of delivery with the treatment manual and to examine the accuracy of the progress sheet information and feedback to the researcher to ensure smooth running of ILAT and adherence to the protocol.

Assessment of Study Design

A series of qualitative interviews with participants as well as all assistants and volunteers will be completed by the PhD student to provide a description of the acceptability of the design and procedures used in the trial and ILAT. The patient interviews will be completed in their homes (or agreed convenient private location) and the assistant/volunteer interviews will be completed in private locations, as agreed with the researcher. All patients will provide informed consent to participate in the interview, which will also be video recorded and transferred to a secure area on the University of Sheffield server. All interviews will be transcribed. The transcripts will not include any personal identifiers and the recordings will be deleted upon completion of the transcription.

Summary of Usual Care

Participants allocated to usual care will continue to attend SLT or support groups as is normal.

Clinical Outcomes

Descriptive statistics will be presented for the clinical outcomes. For continuous outcomes, mean differences between groups along with 95% confidence intervals will be presented. For the primary clinical outcome (TOM's) Activity and Impairment scales at 4-months, the intra-cluster correlation (ICC) for patients treated with the same therapist will be estimated.

Efficacy

The following efficacy outcomes measured at 4-months will be presented by group and overall:

- COAST
- Carerqol-7D
- Carer COAST
- EQ5DL Aphasia Friendly
- EQ5DL Proxy
- TOMs Activity and Participation
- CAT Naming
- CAT picture description

The effect size for the 4-month clinical outcomes listed above will be calculated with baseline outcome as a covariate to allow adjustment for baseline. The effect size is the difference in mean scores between the ILAT group and the usual care group following adjustment for baseline along with the associated 95% confidence interval. This difference and its associated confidence interval will be used to check that the likely effect is within a clinically relevant range and to inform the sample size calculation for the definitive study as outlined in Section 8.

An example of the table of these results can be seen in Section 10.2.

Safety

Safety will be assessed by recording adverse events (AEs). If AEs occur, this will be recorded by the SLT assessor on the CRF and database. For the purposes of this study, adverse events are defined as increased tiredness. All AEs will be assessed for seriousness, expectedness and causality. In addition, for additional events that are classed as serious, including death; a life-threatening AE; inpatient hospitalisation or prolongation of existing hospitalisation; disability or incapacity, the researcher SLT will complete a Serious Adverse Event (SAE) form. For other AEs, the researcher will complete an Adverse Event form. Further stroke related events will not be reported as SAEs because these are expected within this population.

Any patient who experiences an AE may be withdrawn from the study at the discretion of the Investigator.

Researchers will ask patients about any AEs at the 4 month follow-up. This information will be collected on outcome questionnaires, or recorded in person for those participants who require help at a home visit. Any AEs that are self-reported by patients in the intervention group during the delivery of the therapy sessions will also be recorded by the therapist on the CRF and database.

The following figures will be presented:

- The number and percentage of patients reporting an AE;
- The number and percentage of patients reporting a SAE;
- The number and percentage of patients reporting a treatment related AE;
- A list of all AEs and their details.

Detailed Statistical Methods and Calculations

Missing Spurious & Unused Data

Missing data will be reported as described in Section 6.3.

Implementation of the Analysis Plan

This SAP will be used as a work description for the statistician involved in the trial. All analyses will be performed by a the research SLT under the supervision of a statistician based within CTRU (under the supervision of Senior Trial Statistician).

Initially, the data manager will provide blinded data for preliminary checks by the statistician. Due to the nature of the data it is not feasible for blinded randomisation codes to be released before database lock. Following database freeze, unblinded data will be delivered to the statistician to define analysis sets and test statistical programs. Any queries will be communicated to the study and data manager prior to database lock. The database will be locked after agreement between the statistician, data manager and study manager. No changes will be made once the data has been locked, Database freeze and lock will be conducted in accordance with Standard Operating Procedure (SOP) DM012.

Modifications to the Original Protocol Analysis Statement

There are no modifications to the original protocol analysis statement.

References

Trial Documents

Title	Version	Date	Location
Study Protocol	1.1		

CTRU Standard Operating Procedures

Title	Version	Date	Location
ST007 Randomisation	1	Effective 15th October 2014	N:\projects\CTRU\Quality Assurance\SOPs
DM012 Study database lock and retention	3	24th March 2014	N:\projects\CTRU\Quality Assurance\SOPs\Current SOPs

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Appendix 24 Participant Topic Guides

Intensive Language Action Therapy Pilot
Interview topic guide – Participants intervention arm (ILAT)

1. How much does your communication problem affect your life? [scale: not very much – a lot]
    - Do you have trouble talking to people?
    - Do you avoid talking to some people?
    - Is there anyone you enjoy talking with?
    - Has your communication gotten any better since your stroke?
    - When did your communication problem start
    - What parts of your life does your communication problem impact?
    - Has it got worse, better or stayed the same?
    - Can you tell me more about how your communication problem affects your life?

2. How important is it to you that your communication problem improves [scale: not very much – a lot]
    - How important was speech to you before your stroke?

- Do you think your communication has the potential to get better?

3. How much speech therapy have you had before? [not very much – a lot]
    - Would you have liked more therapy than you received?
    - Can you tell me about the speech therapy you have had before?
        - Did it work for you?
    - Of the speech therapy you had in the past what did you find most helpful?

4. What did you think when you first heard about the intensive group therapy? [show pictures to choose from]
    - Did you think you would be able to do the group therapy?
    - Did you think the therapy would help you to talk more easily?
    - Did you have any goals you set for yourself?
    - What did you expect to achieve from doing the group therapy?
    - What does success look like/how will you know you have done well in the therapy?

5. Did you enjoy the group therapy? [not very much – a lot]
    - What was good? What was bad?
    - What was easy? What was hard?
    - What things helped you during the group therapy? What things made the group therapy harder?
    - Can you tell me any more about your experiences/what happened during the group therapy?
    - Is there anything you think would have made the group therapy better?

6. [Insert SLTA/volunteer name] ran the course you attended. Did you feel [insert SLTA/volunteer name] supported you during the therapy? [not very much – a lot]
    - How did [insert SLTA/volunteer name] support you during the therapy?

7. How confident did you feel about having a go during the group therapy? [not very much – a lot]
    - Did you ever feel uncomfortable or upset?
    - What things helped you to feel more confident to try to talk during the therapy?
    - What things made you feel uncomfortable during the group therapy?
    - Can you tell me any more about how you felt during the group therapy?

8. Do you often feel tired? [not very much – a lot]
    - Did the group therapy make you feel more tired? [not very much – a lot]
    - Was the group therapy [too much, just right, not enough]?

- Would you change how much or how often you attended the group therapy?

9. Did you like being in a group with other people with aphasia? [not very much – a lot]
   - What did you like about being in a group for therapy? What didn't you like about being in a group for therapy
   - Tell me more about doing the therapy in a group with other people with aphasia?

10. Is there anything else you would like to tell me?

Intensive Language Action Therapy Pilot
Interview topic guide – Participants usual care arm

1. Did you enjoy being part of the research? [not very much – a lot]
   - What things did you enjoy about the research?
   - What things did you not like about the research?
   - What would you change about the research?

2. What did you think when you first heard about the intensive group therapy? [show pictures to choose from]

3. How easy did you find completing the assessments? [difficult – easy]

4. Were the assessments [too much, just right, too little]?

5. Is there anything else you would like to tell me about the research?

Intensive Language Action Therapy Pilot
Interview topic guide – SLTA/volunteers

1. Tell me about your experience during the ILAT group?
   - What did you enjoy?
   - What did you find challenging?
   - Would you change anything about facilitating the group therapy?

2. Tell me about the training. Was it too much, just right, too little?
    - Was there anything you wished you had been told during training?

3. Tell me about the supervision? Was it too much, just right, too little?
    - Would you change anything about the supervision?

4. How many days of ILAT did you facilitate? Was that too much, just right, too little?
    - How many days would you have liked to facilitate?

5. Tell me about completing the observation record?
    - Is there anything you would change about the observation record?

6. Is there anything else you would like to tell me about facilitating the group therapy?