ISRCTN12514767 https://doi.org/10.1186/ISRCTN12514767

# Pilot trial of Intensive Language Action Therapy - assessing efficient delivery methods

**Submission date**
26/07/2016

**Recruitment status**
No longer recruiting

**Registration date**
28/06/2018

**Overall study status**
Completed

**Last Edited**
28/06/2018

**Condition category**
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Aphasia is an acquired language disorder and is a common and devastating consequence of stroke. 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 an intensively delivered therapy that aims to improve the ability of people with aphasia to speak and has shown to be a promising intervention in early studies. 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. The use of other means of communication such as gesture or pointing is restricted in order to focus on spoken language use. Speech and language therapy (SLT) assistants or volunteers may be able to deliver ILAT under the supervision of a SLT, which would reduce the resources needed to provide this intensive therapy and therefore make it available on the NHS. The aim of this study is to test out whether it is feasible to deliver ILAT with SLT assistants and volunteers under SLT supervision in the NHS, and to test out if it is feasible to conduct a study comparing ILAT to usual care.

Who can participate?
Patients with aphasia, volunteers, carers and SLT assistants

What does the study involve?
Patients are randomly allocated to receive usual care or ILAT. Those assigned to ILAT are then grouped together with people with similar severity of aphasia for a course of ILAT. ILAT is provided face-to-face in a group of up to four patients with two facilitators, either SLT assistants or volunteers. Patients attend therapy for 4 hours a day for 10 working days (Monday-Friday). Usual care is usual SLT care for aphasia. Patients complete assessments that focus on how many and how accurately they can say words and sentences and how well they can speak with other people in everyday life. The assessment also looks at how patients and their carers feel about their communication. These assessments are completed at the start of the study and 4 months later. People with aphasia, SLT assistants and volunteers who participate in the study are invited to participate in an interview to discuss their perceptions, experiences and whether ILAT is

acceptable when delivered by SLT assistants and volunteers. These interviews are completed about 2 weeks after completing a course of ILAT. Patients assigned to usual SLT care are asked about their experiences of participating in the study after 4 months.

What are the possible benefits and risks of participating?
This study will provide important information to determine if ILAT can be used in the NHS delivered by SLT assistants and volunteers. If this is the case then there is the potential for people with aphasia to receive intensive therapy without needing to increase the amount of therapist time.

Where is the study run from?
Northern Lincolnshire and Goole NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2016 to March 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Nicola Crook
nkcrook1@sheffield.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Mrs Nicola Crook

### Contact details
School of Health and Related Research
103 Innovation Centre
217 Portobello Road
Sheffield
United Kingdom
S1 4DP
+44 (0)1724290043
nkcrook1@sheffield.ac.uk

# Additional identifiers

### Protocol serial number
URMS 144796; 31460

# Study information

### Scientific 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

## Study objectives
1. Is it feasible to carry out a randomised control trial to investigate whether intensive language action therapy (ILAT) facilitated by trained assistants/laypersons is clinically and cost effective?
2. Is ILAT facilitated by trained assistants/laypersons feasible to deliver and acceptable to all stakeholders?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Yorkshire and the Humber – Bradford Leeds Research Ethics Committee, 12/10/2016, ref: 16/YH /0344

## Primary study design
Interventional

## Study design
Pragmatic parallel group randomised controlled pilot trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Aphasia post stroke

## Interventions
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.

Intensive Language Action Therapy will be provided face-to-face in a group of up to four participants with two facilitators, either SLT assistants or volunteers. Participants attend therapy for 4 hours a day for 10 working days (Monday-Friday). The comparison intervention is usual Speech and Language Therapy care for aphasia.

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 (Speech and Language Therapy Assistants/volunteers). Semi-structured interviews will explore facilitators and barriers to success during ILAT.

## Intervention Type
Behavioural

## Primary outcome(s)

The primary aim 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, the primary outcomes are;
1. Feasibility of recruitment to the main trial – number of participants recruited per month and in a 12-month period
2. Acceptability of the research procedures, as described by participants through interviews
3. 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 4-month outcome measures completed within 1 month of the 4-month post randomisation timepoint
4. 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

## Key secondary outcome(s)

Secondary outcomes
The secondary outcomes examine the feasibility of delivering ILAT using assistants and volunteers based on the following;
1. Acceptability of ILAT to participants, assistants and volunteers, as described by participants through qualitative interviews collected after participation in a treatment course
2. 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, collected during each treatment course
3. Treatment fidelity of ILAT, measured through the observation/video recording and analysis of a sample of treatment sessions
4. Facilitators and barriers to ILAT success, as described by participants through qualitative interviews collected after completion of a treatment course

Clinical outcomes
The primary clinical outcome measure is conversational ability at 4 months measured through video-recorded conversations rated 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;
1. Naming ability and sentence production measured using the Comprehensive Aphasia Test Subtests: Naming objects and picture description (Swinburn, Porter & Howard, 2004) at baseline and 4 months
2. Participant rated perceptions of communication ability measured using the Communication Outcome After Stroke (patient rated outcome measure) (Long et al, 2008) at baseline and 4 months
3. Carers perceptions of participant communication ability measured using the Carer Communication Outcome After Stroke (carer rating of participant communication) (Long et al, 2008) at baseline and 4 months
4. Health related quality of life measured using the EQ-5D-5L aphasia friendly version and proxy

rated EQ-5D-5L (Janssen et al, 2015) at baseline and 4 months
5. Carer health related quality of life measured using the Carer QoL (Brouwer et al, 2006) at baseline and 4 months

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.

### Completion date
31/03/2019

# Eligibility

### Key inclusion criteria
Participants:
Participants who have aphasia at least one-month post stroke will be identified by therapists from within speech therapy databases or by the Stroke Association Communication Support worker. The research SLT will then screen potential participants using the following criteria, which were devised in line with previous studies of ILAT (Pulvermuller et al, 2001, Meinzer et al, 2007);
1. Participants with aphasia as a consequence of stroke (determined by research SLT)
2. Participants must be able to repeat spoken words (determined by research SLT)

Volunteers:
Volunteers will be identified through advertising with volunteering agencies such as Voluntary Action and the Stroke Association. Volunteers who are already working with in Northern Lincolnshire and Goole NHS Foundation Trust will also be invited express interest in this role.
1. Expressed interest in the role
2. Be a competent communicator as determined at interview
3. Be dynamic, patient and encouraging as determined at interview
4. Agree to criminal records and health checks
5. Be able to participate for a minimum of 8 hours per treatment group
6. Be able to attend training
All volunteers will be 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 will sign a code of conduct in accordance with the Department of Health's (2011) volunteer guidelines and trust volunteering procedure.

Carers:
Carer participants are eligible to take part in the trial if they provide informal care to the trial participant including family members, spouses and friends.

Speech and Language Therapy Assistants (SLTAs):
A previous agreement has been made within the Speech and Language Therapy team to release SLTAs already working within the trust to participate in this trial. All SLTAs working within the trust will be eligible to participation in the trial. All SLTAs will have undergone DBS, health checks and induction and mandatory training in line with NHS employee requirements.

### Participant type(s)
Mixed

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
Participants:
1. Participants must not have any other cognitive or psychological conditions that would affect participation or consent such as memory problems, dementia or difficulties with attention as judged by consenting research SLT
2. Participants must not have 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. Currently receiving intensive therapy at more than 2 hours of individual therapy per week

Volunteers:
Must not have any formal SLT training or experience with ILAT

Carers:
Does not meet inclusion criteria

SLTAs:
Does not meet inclusion criteria

### Date of first enrolment
01/10/2016

### Date of final enrolment
01/02/2018

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Northern Lincolnshire and Goole NHS Foundation Trust**
United Kingdom
DN15 7HB

# Sponsor information

**Organisation**
University of Sheffield

**ROR**
https://ror.org/05krs5044

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets will be anonymised and compiled and placed on ORDA (https://orda.shef.ac.uk). Data will be available 1 year after the trial has closed. Participants have consented to data being compiled and used in further research. The University of Sheffield will hold the data on ORDA.

**IPD sharing plan summary**
Stored in repository

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |