ISRCTN71455409 https://doi.org/10.1186/ISRCTN71455409

Investigation of different therapy approaches for aphasia in the Greek language

Submission date
27/05/2018

Recruitment status
No longer recruiting

Registration date
12/06/2018

Overall study status
Completed

Last Edited
08/11/2019

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
About a third of people who have a stroke, have aphasia. Aphasia is a language disorder that can affect speaking, understanding what people say, reading and writing. Most people with aphasia have difficulty finding the words they want to say. In this study we looked at whether a specific speech and language therapy could improve word-finding for people with aphasia. The therapy is called Elaborated Semantic Feature Analysis (ESFA). We compared a group of people who had ESFA to a group of people on a waiting list. We also looked at whether there were any differences in outcomes if people had ESFA one-to-one with a speech and language therapist versus if they had ESFA in a combination of one-to-one sessions and group therapy.

Who can participate?
People with aphasia due to stroke at least 4 months after they had their stroke. Participants had to be over 18 years old and have no significant cognitive problems.

What does the study involve?
By the end of the study, all participants had 3 hours of ESFA therapy per week for 12 weeks (36 hours in total). Those who had one-to-one ESFA had three 1-hour sessions per week with a speech and language therapist. Those that had combination ESFA had two 45-min one-to-one sessions with the speech and language therapist and one 90-min group session with other people with aphasia and the speech and language therapist.

What are the possible benefits and risks of participating?
By taking part in this study, people receive speech and language therapy which can help them improve their word finding skills. They may also find it easier to communicate with other people and they may experience improved feelings of quality of life. There are no known risks in taking part in this study.

Where is the study run from?
The lead centre of this study is Eginitio Hospital in Athens, Greece. There are also another six hospitals/rehabilitation centres in Athens and the University General Hospital of Patras taking part.

When is the study starting and how long is it expected to run for?
The study started in January 2012 and finished in November 2015.

How long will the trial be recruiting participants for?
The study recruited participants between February 2013 and March 2015. The study was funded by the European Union (European Social Fund – ESF) and Greek national funds through the Operational Program "Education and Lifelong Learning" of the National Strategic Reference Framework (NSRF).

Who is the main contact?
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Protocol serial number
70/3/11672

Study information

Scientific Title
Efficacy of elaborated semantic features analysis in aphasia: a quasi-randomised controlled trial

Acronym
Thales Aphasia: SLT

Study objectives
1. Evaluate the efficacy of Elaborated Semantic Features Analysis (ESFA) for people with aphasia on different domains of the WHO ICF (International Classification of Functioning, Disability and Health) framework, including quality of life, as compared to a delayed-treatment control group. It was hypothesised that the therapy group will have improved language skills, while the delayed-treatment control group will not. It was also hypothesised that ESFA, although specifically targeting the underlying language impairment, could lead to secondary gains in other levels of the WHO ICF model, such as communication, and quality of life.
2. Compare and contrast the relative efficacy of ESFA therapy on different domains of the WHO ICF framework, and quality of life, as delivered in two different approaches - direct (individual) and indirect combination therapy (individual and group). It was hypothesised that direct therapy (individual therapy) will lead to greater benefits on participants' language skills (naming), while indirect therapy (combination therapy) will lead to greater benefits on functional communication, i.e. the ability of people to get their message across, using whatever means they can. Combination therapy (individual and group therapy) may potentially have a greater effect on participants' well-being and life quality due to the reported psychosocial benefits of groups therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was obtained in both Greece and the United Kingdom. In Greece, the project was evaluated by two research ethics committees: The University Hospital of Patras (approved 25/02/2013, 42/19.02.2013), for participants recruited in Achaia, and the University of Athens Eginitio Hospital (approved 02/06/2013, 325/16-01-13) for participants recruited in Attica. In the UK, the project was approved by the Division of Language and Communication Science's Proportionate Review Committee of the School of Health Sciences, City, University of London (approved 21/08/2013, PhD/12-13/17).

Study design
Quasi-randomized single-blind controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Aphasia due to stroke

Interventions
Participants were randomised based on the order of their enrolment in the study. It is quasi-randomised for two main reasons. Firstly participants were randomized after enrolment to the overall Thales project and before eligibility for speech and language therapy was checked. This resulted in participants being excluded for not meeting eligibility criteria after randomization and therefore uneven numbers in the groups. Secondly participants were randomized to one of three groups: direct therapy, combination therapy, delayed treatment. Therapies offered were either Elaborated Semantic Features Analysis (ESFA) or mapping therapy. This study reports on those who were allocated to ESFA therapy. The decision on whether a person with aphasia would receive ESFA or mapping therapy was based on their language deficits according to the Boston Diagnostic Aphasia Examination.

The intervention tested was ESFA, which has been previously described in detail and has good evidence of treatment fidelity (Kladouchou et al., 2017). In summary, participants received either 36 h of individual therapy (three 1-h sessions per week for 12 weeks) or 36 h of a combination of individual and group therapy (two 45-min individual therapy sessions and one 1.5 h group session per week for 12 weeks). The sessions took place mainly in the participants' home and some in hospital settings. In therapy, the client chose a picture from a stimuli set and the therapist asked them to name it. Then, presenting a semantic feature chart (as in Boyle 2004), the therapist prompted the client to think of and say words related semantically with the target word (semantic features). The chart included six categories: superordinate category, use, action, physical properties, location and association. To elicit features, the therapist asked questions or provided the client with sentence completion cues while prompting them to write down the features generated. If needed, the therapist used an alphabet board to help clients write; and if they were unable to write, the therapist filled in the chart. Then the client was prompted to produce phrases with the target word and each of its features. In group therapy sessions, the same procedure was followed with participants asked in turn to complete the chart and produce phrases. In time, the therapist gave participants the opportunity to interact and provide appropriate cues to each other. The therapist controlled turn taking to ensure individuals got similar amounts of exposure to targets and cues, whilst being mindful of disturbing peer-to-peer interactions as little as necessary.

To select treatment stimuli, each participant completed an oral confrontation-naming task of the 260 Snodgrass and Vanderwart pictures –colour version (Rossion & Pourtois, 2004) three times before starting therapy. The pictures were presented in a random order to each participant, without any cueing or feedback. It took approximately 60 minutes to administer the full set of pictures, using a computerized task, and participants were given a maximum of 13 seconds to respond to each picture. The pictures that a participant failed to name on at least two trials were selected as potential treatment stimuli. Not all selected treatment items were used during the therapy procedure. Each participant was trained in a subset that was dependent on participant's success on the probes that were taken during the therapy.

The delayed treatment control group had no speech and language therapy while the intervention groups were having therapy.

Intervention Type
Behavioural

Primary outcome(s)
Oral confrontation-naming task of the 260 Snodgrass and Vanderwart pictures – colour version. Participants on the therapy approaches (direct group, combination group) were assessed twice before therapy (double baseline, weeks 1 and 6), post-therapy (week 19), and 3-months later (follow-up). Participants on the delayed treatment control group were assessed three times before therapy (weeks 1, 6 and19) and then were randomly allocated to one of the two approaches for ESFA treatment and were reassessed after the 12-week treatment (post-therapy) and 3 months later (follow-up).

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

Key secondary outcome(s))
1. Greek Boston Naming Test (Simos, Kasselimis & Mouzaki, 2011)
2. Functional communication skills assessed using American Speech and Hearing Association Functional Assessment of Communication Skills for Adults (ASHA FACS) (Frattali et al., Holland, Thompson, Wohl, & Ferketic, 1995), which was completed by the partner / main carer of the participant with aphasia
3. Discourse scores from the Cookie Theft Picture Description of the BDAE (BDAE; Goodglass & Kaplan, 1983)
4. Emotional distress assessed using the Greek version of the General Health Questionnaire-12, (GHQ-12, Garyfallos et al., 2001)
5. Quality of life assessed using the Greek version of the Stroke and Aphasia Quality of Life Scale-39g scale (SAQOL-39g, Kartsona & Hilari, 2007; Efstratiadou et al., 2012)
6. Health status assessed using the Greek version of EQ-5D (Kontodimopoulos, 2008).

Secondary outcomes were assessed at the same time points as the primary outcome. The same analyses were carried out for the secondary outcome measures as for the primary outcome.

Completion date
30/11/2015

Eligibility

Key inclusion criteria
1. Aphasia following stroke, as reported by their referring clinician
2. >4 months post stroke and medically stable
3. Greek native speakers
4. Aged over 18 years
5. No significant cognitive decline (scored ≥32 out of 38 on Brief Cognitive Screening Test [Economou & Routsis, 2015], a test specifically developed for people with aphasia)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. Not living at home prior to stroke
2. Known history of mental health problems and/or cognitive decline prior to stroke
3. History of other neurological or psychiatric problems
4. Received other speech language therapy during this research

Date of first enrolment
22/02/2013

Date of final enrolment
16/03/2015

Locations

Countries of recruitment
Greece

Study participating centre
Eginitio Hospital
Athens
Greece
GR-11528

Study participating centre
General State Hospital- George Gennimatas
Athens
Greece
GR-11517

Study participating centre
Evaggelismos Hospital
Athens
Greece
GR-10676

Study participating centre
University General Hospital - Attikon
Athens
Greece
GR-12462

Study participating centre
Filoktitis Rehabilitation Centre
Athens
Greece
GR-19400

Study participating centre
Iatriki Askisis Rehabilitation Centre
Athens
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Sponsor information

Organisation
University of Athens

ROR
https://ror.org/03xawq568

Funder(s)

Funder type
Not defined

Funder Name
European Union (European Social Fund – ESF)

Funder Name
Greek national funds through the Operational Program "Education and Lifelong Learning" of the National Strategic Reference Framework (NSRF)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/12/2019	08/11/2019	Yes	No
Participant information sheet		07/06/2018	02/04/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes