Efficacy of Elaborated Semantic Features Analysis in Aphasia: a quasi-randomised controlled trial

Evangelia – Antonia Efstratiadou[1], Ilias Papathanasiou[2], Rachel Holland[1], Spyridoula Varlokosta[3], and Katerina Hilari[1]

[1]Division of Language and Communication Science, School of Health Sciences, City, University of London, UK

[2]Department of Speech and Language Therapy, Technological Educational Institute of Western Greece, Greece

[3]Department of Linguistics, School of Philosophy, National and Kapodistrian University of Athens, Greece

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Corresponding author: Professor Katerina Hilari k.hilari@city.ac.uk

Abstract

Background: Word finding difficulty is one of the most common features of aphasia. Semantic Features Analysis (SFA) directly aims to improve word finding in people with aphasia. Evidence from systematic reviews suggests that SFA leads to positive outcomes, yet the evidence comprises single case studies and case series. There is a need to evaluate the efficacy of SFA in controlled group studies/trials.

Aims: To evaluate the efficacy of Elaborated Semantic Feature Analysis (ESFA) for word finding in people with aphasia. We investigated: (a) the efficacy of ESFA versus a delayed therapy/control, (b) the efficacy of two therapy approaches– individual versus a combination of individual and group therapy.

Methods and procedures: We ran a multi-centre, quasi-randomised controlled trial, nested in a larger study (Thales-Aphasia). Participants were recruited from community settings. They had to be people with aphasia due to stroke at least four months post-onset. Participants were randomized to individual vs combination vs delayed therapy/control groups. Both therapy groups had three hours of ESFA per week for 12 weeks. Delayed therapy/control group had no intervention for 12 weeks and were then randomized to either individual or combination therapy. The primary outcome was confrontation naming. Secondary outcomes were the Boston Naming Test, Discourse, the Functional Assessment of Communication Skills for adults (ASHA–FACS), the Stroke and Aphasia Quality of Life scale (SAQOL-39g), the General Health Questionnaire-12 item, and the EQ-5D.

Outcomes and Results: Of the 72 participants of the Thales-Aphasia project, 58 met eligibility criteria for speech-language therapy and 39 were allocated to ESFA. The critical p-value was adjusted for multiple comparisons (.005). For the therapy versus control comparison, there was a significant main effect of time on the primary outcome ($p<.001$, $\eta^2_p=.42$) and a significant interaction effect ($p=.003$, $\eta^2_p=.21$). An interaction effect for the SAQOL-39g ($p=.015$, $\eta^2_p=.11$) and its psychosocial domain ($p=.013$, $\eta^2_p=.12$) did not remain significant after Bonferroni adjustment. For the individual versus combination ESFA comparison, there were significant main effects of time on the primary outcome ($p<.001$, $\eta^2_p=.49$), the BNT ($p<.001$, $\eta^2_p=.29$) and the ASHA-FACS ($p=.001$, $\eta^2_p=.18$). Interaction and group effects were not significant.

Conclusion: Though underpowered, this study provides evidence on the efficacy of ESFA to improve word finding in aphasia, with gains similar in the two therapy approaches.

Trial registration: ISRCTN71455409, https://doi.org/10.1186/ISRCTN71455409

Keywords

Aphasia; Therapy; Elaborated Semantic Features Analysis; Efficacy; Randomised Controlled Trial.

Introduction

The most common cause of aphasia is a stroke. It is estimated that 45% of people with stroke have aphasia, with 24% having persistent problems (Ali, Lyden & Brady, 2015). Stroke survivors with aphasia are less likely to survive than those without (Laska, Hellblom, Murray, Kahan & Von Arbin, 2001); and tend to have worse rehabilitation outcomes (Astrom, Adolfsson & Asplund, 1993). Aphasia has a profound impact on people's lives, with consequences including social isolation and poor quality of life for themselves and their family members (Grawburg, Howe, Worrall & Scarinci, 2013; Hilari, Needle & Harrison, 2012; Winkler, Bedford, Northcott & Hilari, 2014; Northcott, Moss, Harrison & Hilari, 2016).

Aphasia severity and communication disability are predictors of health related quality of life in people with aphasia post stroke (Hilari et al., 2012). Reducing the impairment caused by aphasia may alleviate some of its negative consequences. One of the most common features of aphasia is difficulty finding the words one wants to say. Naming therapies directly aim to address word finding difficulties and have been extensively tested in the aphasia literature using case studies and case series. A recent Cochrane review identified only seven trials (275 participants) evaluating naming outcomes in aphasia and graded the quality of the evidence as low (Brady, Godwin, Enderby, Kelly & Campbell, 2016).

A therapy that directly aims to improve naming and word finding in people with aphasia is Semantic Features Analysis (SFA, Boyle, 2010). SFA aims to improve retrieval of words by stimulating semantic networks. During SFA treatment, the person with aphasia is guided to produce words semantically related to the target. For example, for 'dog', questions like 'what is it?', 'what does it do?' are asked to generate its semantic features, such as 'it's an animal', 'it's a pet', 'it barks', 'it wags its tail'. According to the spreading activation theory of semantic processing (Collins & Loftus, 1975), activating the semantic network surrounding the target should activate the target itself, thus facilitating retrieval of the word. Evidence from two systematic reviews and meta-analyses suggests that SFA leads to positive outcomes on naming despite variability in treatment procedures, dosage, and duration; with limited generalization to untrained items and connected speech (Efstratiadou, Papathanasiou, Holland, Archonti & Hilari, 2018; Oh, Eom, Park & Sung, 2016). None of the included studies in these meta-analyses were controlled trials.

This study aimed to investigate the efficacy of SFA in a controlled trial/group design. To the best of our knowledge, it is the first study to do this. To encourage generalization to connected speech, the elaborated version of SFA (ESFA) was used (Papathanasiou & Mihou, 2006), whereby, once the word is retrieved, the person with aphasia is asked to use it together with its semantic features in a phrase or sentence, e.g., 'the dog is wagging its tail'. A second aim of the study was to explore if different approaches to delivering the therapy led to different outcomes: individual therapy vs. a combination of individual and group therapy. Based on the literature and given that group therapy involves increased interaction with other people with aphasia, we hypothesized

that it may lead to greater gains in functional communication (Elman, 2007); and potentially well-being and quality of life (Ownsworth, Fleming, Shum, Kuipers & Strong, 2008). The specific objectives of the study were to:

1) Evaluate the efficacy of ESFA therapy for people with aphasia, as compared to a delayed treatment control group.
2) Evaluate the relative efficacy of ESFA therapy, as delivered in two different approaches - individual and combination (individual and group) therapy.

Methods

The Consolidated Standards of Reporting Trials (CONSORT) 2010 Statement (www.consort-statement.org) was followed in reporting this study and the CONSORT Checklist is provided as supplementary material. The study is registered with the WHO International Standards Randomised Controlled Trials Number (ISRCTN) Registry, identification number ISRCTN71455409 https://doi.org/10.1186/ISRCTN71455409 .

Context: This study was nested within the Speech and Language Therapy stream of the Thales-Aphasia project "Levels of impairment in Greek Aphasia: relationship with processing deficits, brain region and therapeutic implications", http://thales-aphasia.phil.uoa.gr/, the largest investigation of aphasia and people with aphasia in Greece. The Speech and Language Therapy stream aimed to investigate the efficacy of word level (ESFA) and sentence level therapy (mapping therapy) for aphasia. In this paper we report on the efficacy of word level therapy (ESFA)

Ethics: 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 (42/19.02.2013), for participants recruited in Achaia, and the University of Athens Eginitio Hospital (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 (PhD/12-13/17).

Design: This study is a quasi-randomized, single blinded controlled trial with a delayed treatment control group. Participants were randomized based on the order of their enrolment in the study. It is quasi-randomized for three reasons: i) participants were randomized after enrolment to the overall Thales-Aphasia 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. ii) participants were randomized to one of three groups: direct therapy, combination therapy, control/delayed therapy. 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 whether they had primarily word finding difficulties (ESFA) or sentence level difficulties (mapping). We determined this based on the aphasia severity rating scale of the Boston Diagnostic

Aphasia Examination (BDAE Greek version, Papathanasiou, Papadimitriou, Gavrilou & Mihou, 2008) and their naming on the Boston Naming Test (BNT Greek version, Simos, Kasselimis & Mouzaki, 2011). If they scored lower than 5/7 on 80% of the BDAE aphasia severity rating scale items (excluding auditory comprehension) and lower than 20/45 on the BNT, they were allocated to ESFA. iii) The randomization process was modified during the trial (see 'Changes to methods after trial start below).

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

Link clinicians from the recruiting sites referred potential participants to four neuropsychologists of the Thales-Aphasia project. The Thales-Aphasia neuropsychologists visited potential participants, provided information on the project using aphasia friendly information sheets, and answered any questions participants may have had. They asked those interested to take part for permission to access their medical records in order to obtain information about stroke and relevant medical history and check eligibility for the study. Those eligible were visited again, screened for cognition and written consent was obtained.

Sample size: For a mixed (within and between subjects) ANOVA to achieve a medium effect size ($f = 0.25$), at an alpha level of $p = 0.05$, a total sample of 78 participants gave 80% power; and a sample size of 92 gave 85% power. We aimed to recruit 96 participants to allow for attrition, which is common in stroke studies.

Randomization: Participants were randomized by the order of their enrollment in the study. To achieve $n = 96$, we planned to run two cycles of randomization of 16 participants in each of the three groups. The first 16 participants would be randomized to individual therapy, the second 16 to combination therapy, the third 16 to control group ($16x3 = 48$), and then the cycle would be repeated ($48x2 = 96$). The neuropsychologists entered participants as they were enrolled into the study in a shared excel file, where randomization allocation was pre-marked by the trial manager. The trial manager was one of the Thales-Aphasia project treating speech and language therapists, who had no contact with participants until after randomization and baseline assessments were completed. In terms of intervention assignment, as indicated above, whether participants had individual or combination therapy was determined by their enrollment order; whether they had ESFA or mapping therapy was determined by the Thales-Aphasia project

assessing speech and language therapists (Assessors) based on their baseline language scores as detailed above.

Blinding: The study was single-blinded. The Assessors who carried out all assessments and outcome measurements were blinded to participant group allocation. To ensure they remained blinded, they did not share an office with other researchers in the Thales-Aphasia project and they had no access to electronic datasets until data collection was finished. As this was a behavioural intervention, neither participants nor therapists delivering the intervention were blinded.

Changes to methods after trial start: Originally, the study aimed to evaluate group therapy as well, but this was abandoned early in the study, as participants would only agree to have group therapy if they also had individual therapy with a speech and language therapist (i.e. combination therapy). This amendment received ethics approval. The randomization cycles were also modified. First, due to a clerical error 18 participants were randomized to each of the three groups (direct, combination, delayed treatment control) in the first randomization cycle (n = 54). Second, within the first randomization cycle, participant recruitment became increasingly slower and it became apparent that the planned sample size would not be reached within the timeframe of the project. As this study employed a delayed treatment control group, to ensure that as many participants as possible completed treatment and follow-up assessment before the project ended, no more participants were allocated to the control group after the first randomization cycle. Additionally, to ensure a more even allocation between direct and combination therapy, we decided to run more randomization cycles with a smaller number randomized in each group in each cycle. Three more randomization cycles ran with 10 participants allocated to either direct or combination therapy in the second cycle, and four participants in the third and fourth cycle. As a result, 27 participants were randomized to direct speech and language therapy (18+5+2+2), 27 to combination therapy (18+5+2+2) and 18 to control/delayed therapy (total n = 72). Not all of these participants completed the study (see results).

Procedure: After consent, the Thales-Aphasia neuropsychologists referred participants to the Thales-Aphasia Assessors. These were two speech and language therapists who were blinded to group allocation. Thales-Aphasia Assessors performed all assessments. Two baseline assessments were carried out: one at study entry (week 1) and one six weeks later (week 6). Each assessment was completed in two sessions (each ranged from 90 to 120 minutes). Those who were allocated to a treatment condition commenced therapy at that point. They received therapy by a Thales-Aphasia treating speech and language therapist for 12 weeks. Those allocated to the control group had 12 weeks of no contact with the Speech and Language Therapy research team. Participants were assessed again at that stage (week 19, post-therapy for those in treatment groups). Delayed therapy control group participants were then randomly allocated to individual or combination therapy and received therapy for 12 weeks. All participants were assessed again at that stage (week 32, follow-up for those in treatment groups, post-therapy for those in control). Delayed therapy group participants were assessed again 12 weeks later (week 45, follow-up). Figure 1 illustrates participant flow in the study.

Intervention: The intervention tested was ESFA, which has been previously described in detail, including a Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014), and has good evidence of treatment fidelity (Kladouchou, Papathanasiou, Efstratiadou, Christaki & Hilari, 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 participant chose a picture from a stimulus set and the therapist asked them to name it. Then, presenting a semantic feature chart (as in Boyle, 2004), the therapist prompted the participant 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 participant with sentence completion cues. As part of the elaborated element of SFA used in this study, the therapist also asked the participant to write down the features generated. If needed, the therapist used an alphabet board to help participants write; and if they were unable to write, the therapist filled in the chart. Then the participant 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 cuing or feedback. It took approximately 60 minutes to administer the full set of pictures, using a computerized task, and participants were given a maximum of 13 seconds to respond 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 therapy. Each participant was trained in a subset that was dependent on participant's success on the probes that were taken during the therapy.

Measures: The Greek version of the BDAE was used as a profiling measure to provide information on participants' aphasia type and severity. The primary outcome measure was the oral confrontation-naming task of the 260 Snodgrass and Vanderwart pictures – colour version. Secondary outcome measures comprised the Greek BNT; the American Speech and Hearing Association Functional Assessment of Communication Skills for Adults (ASHA FACS) (Frattali, Thompson, Holland, Wohl & Ferketic,1995a,1995b), which was completed by the partner / main carer of the participant with aphasia; discourse scores from the Cookie Theft Picture Description of the BDAE (BDAE; Goodglass & Kaplan, 1983): correct information units per min (CIU/min, Nicholas & Brookshire, 1993); Greek version of the General Health Questionnaire-12, (GHQ-12, Garyfallos et al., 1991); Greek version of the Stroke and

Aphasia Quality of Life Scale-39g scale (SAQOL-39g, Kartsona & Hilari, 2007; Efstratiadou et al., 2012) overall score and three subdomains; Greek version of EQ-5D (Kontodimopoulos et al., 2008).

Data analysis: Descriptive statistics were used to summarize participant characteristics and scores on measures used. As 10 outcome measures were used in this study, a Bonferroni correction was applied (0.5/10 = 0.005) to the critical probability value. To explore whether there was a significant difference between ESFA therapy versus no therapy (control group), mixed ANOVAs were carried out with two levels in the between factor (therapy vs. no therapy) and three levels in the within factor (week 1/baseline 1 (BL1), week 6/baseline 2 (BL2) and week 19, which was after 12 weeks of therapy for the therapy group (Post) and after 12 weeks of no therapy / baseline 3 (BL3) for the control group). To explore the efficacy of individual ESFA vs. combination ESFA therapy approach, mixed ANOVAs were carried out with two levels in the between factor (type of therapy: individual vs. combination) and four levels in the within factor (four assessment time-points: two baselines, post therapy, and follow-up). For the control group the assessment points of week 6 and week 19 were taken as the two baselines. To ensure unbiased comparison among the randomized groups, intention to treat (ITT) analysis was used (Sainani, 2010). ITT avoids overoptimistic estimations of the efficacy of a therapy, which results after removing non-compliers (Gupta, 2011). ITT analysis includes all randomised patients in the groups to which they were randomly assigned, regardless of: a) their adherence with the entry criteria, b) the treatment they received, and c) subsequent withdrawal from the treatment or deviation from the protocol (Fisher *et al*., 1990). The Last Observation Carried Forward (LOCF) method of ITT was used in this study (Gadbury, Coffey & Allison, 2003; Molnar, Hutton & Fergusson, 2008). This technique replaces a participant's missing values after dropout with the last available measurement and assumes that the participant's response would have been stable from the point of the dropout to trial completion, rather than worsening or improving.

[figure 1 about here]

Results

The Thales-Aphasia project recruited a total of 72 participants between 25/02/2013 – 16/03/2015, who were randomized to three groups: individual, combination, control/delayed therapy. Three-month follow up assessments were completed on 30/11/2015. Of the 72 participants, 14 participants were excluded as they: a) did not meet inclusion criteria (n=12), b) declined to participate to therapy (n=1) and c) lived in another city faraway from Athens (n=1). This resulted in uneven numbers of participants in the three groups: direct approach (n=23), combination approach (n=17) and control group – delayed therapy approach (n=18). Figure 1 shows participant flow in the study. Participants from the delayed therapy approach were randomized to direct or combination approach for treatment after the third evaluation (eight to direct and 10 to combination).

Thirty-nine participants were allocated to ESFA (18 from the individual therapy group, nine from the combination group, 12 from the delayed therapy group). At the end of the study 22 individuals had received ESFA with direct, 14 with combination approach, and three had dropped out. No harms or unintended effects were reported. One of the participants who dropped out did not complete the initial assessment process and therefore had no data to contribute to the analysis (ESFA n=38). For the other two participants who started the project and subsequently dropped out, we analysed their data as per ITT, in the therapy versus control / delayed therapy comparison. In the individual versus combination therapy comparison they could not be included in the analysis as they had no data to contribute: both these participants were control group participants who did not start therapy (one dropped out and the other was excluded as he started speech language therapy privately). As a result, findings are presented for:

I) Efficacy of ESFA (individual and combination, n=26) vs. control/delayed treatment (n=12).
II) Efficacy of individual (n=22) vs. combination (n=14) ESFA.

Participant characteristics are presented in table 1 for those in the therapy and those in the control group. The two groups were well matched in terms of their demographic and stroke related characteristics. The therapy group comprised 20 men and 6 women and the control/delayed therapy group 6 men and 6 women. There were no significant differences between the groups in gender, age, marital status, years of education, time post onset, aphasia type, and aphasia severity. In both groups, the majority of participants was non-fluent (21/26 in therapy group; 7/12 in control group) and had severe or moderate aphasia (21/26 in therapy group; 9/12 in control group). A surprising finding was the working status of the participants in our study, with ≥ 50% still working. This high proportion of people with aphasia at work is likely due to Greek legislation. A substantial proportion (16/36) of our sample worked in the public sector and according to Greek legislation persons with aphasia have the right to continue on full pay for as many months' post stroke as years they have worked. They are then assessed to determine their disability percentage. When the percentage is higher than 67% the person with aphasia can leave work on benefits. When the percentage is less than 67%, their employer has to place them in an appropriate work position in the public sector according to their abilities and qualifications. This may explain the large proportion of people who worked in our sample, despite the severity of their aphasia.

[table 1 about here]

I) Efficacy of ESFA vs. control

Changes in scores across time are presented in table 2 and figure 2 together with mixed ANOVA results. On the primary outcome measure, scores for the control group were similar (within 15 points) across the three assessment points. Scores for the therapy group were similar between the two baselines but increased by > 40 points from the

highest baseline to the post therapy evaluation. On the two-way mixed ANOVA, the effect of group was not significant. There was a significant main effect of time, Greenhouse-Geisser F (1.09, 39.38) = 26.04, $p < .001$ with a large effect size ($\eta^2_p = .42$). Pairwise comparisons showed there was a small (mean difference = 6.15) but significant difference between BL1 and BL2 ($p = .002$) and large (mean differences = 31.12 and 24.96) significant differences between both BL1/BL2 and post-therapy/BL3 (ps < .001). Importantly, there was a significant interaction effect Greenhouse-Geisser F (1.09, 39.38) = 9.56, $p = .003$ with a large effect size ($\eta^2_p = .21$), whereby the therapy group improved significantly more from BL2 [mean (SD) = 61.96 (49.50)] to post-therapy [mean (SD) = 104.38 (73.91)] than the control group [74.33 (62.94) and 81.83 (69.90), respectively].

On the secondary outcome measures, there was a significant main effect of time on the BNT, Greenhouse - Geisser F (1.45, 52.14) = 8.37, $p = .002$ with a large effect size ($\eta^2_p = .19$). Pairwise comparisons showed there were significant differences between the two baselines and post-therapy/BL3 ($p = .004$, $p = .036$). Though the increase in scores for the therapy group from BL2 to post-therapy was sharper, the interaction effect was not significant. There was an interaction effect on psychosocial ($p = .013$, $\eta^2_p = .12$) and overall quality of life (SAQOL-39g) ($p = .015$, $\eta^2_p = .11$), with only the therapy group improving from BL2 to post-therapy, but these were not significant after adjusting for multiple comparisons.

[table 2 about here]

[figure 2 about here]

II) Efficacy of individual vs. combination ESFA

In terms of participant characteristics, as above, the groups were well matched on their demographic and stroke related variables. Participants' scores across time and mixed ANOVA results are presented in table 3 and figure 3. On the primary outcome measure the group effect was not significant. There was a significant main effect of time, Greenhouse-Geisser F (1.90, 64.53) = 32.95, $p < .001$ with large effect size ($\eta^2_p = .49$). Pairwise comparisons showed there was a small but significant difference between BL1 and BL2 (mean difference = 10.23, $p = .003$), and large significant differences between the two baselines and post-therapy and between the two baselines and follow-up (mean difference range = 33.22 – 49.69, all ps < .001); the difference between post-therapy and follow-up was not significant. Though the combination group showed a slightly sharper increase from pre to post therapy, the interaction effect was not significant.

On the secondary outcome measures there were no significant group effects. On the BNT, ASHA-FACS, and SAQOL-39 psychosocial and overall score there was a trend for the combination group mean scores to increase more sharply from BL2 to post-therapy and then drop more from post-therapy to follow-up; yet there were no significant interaction effects. The main effect of time was significant for the BNT ($p < .001$, $\eta^2_p = .29$), with significant differences between the two baselines and post therapy (ps < .001) and baseline 1 and follow up ($p = .003$); and for the ASHA-FACS ($p = .001$, $\eta^2_p = .18$), with a significant difference between baseline 1 and follow up ($p = .005$). There was a

time effect for overall quality of life ($p = .046$, $\eta^2_p = .09$), which did not remain significant after adjusting for multiple comparisons.

[table 3 about here]

[figure 3 about here]

Discussion

This is the first study to explore the efficacy of ESFA therapy for people with aphasia utilizing a quasi-randomised controlled trial design, rather than a case-study or case-series approach. We found a significant difference on the primary outcome measure (naming) between the two groups, with the control group showing a small improvement across time, in contrast to the therapy group that improved substantially from pre to post therapy. Unlike the control group, the therapy group also showed improvements in psychosocial and overall quality of life after therapy, but these differences were not significant after adjusting for multiple comparisons.

These findings are important as they provide evidence for the efficacy of ESFA. Changes in naming for the therapy group went over and beyond changes in the control group, which could be attributed to the regular contact and language-related activities that participants had during this time with neurolinguistics and neuropsychology researchers in the broader Thales-Aphasia project; or to familiarity with the assessment task (Dorry & Hough, 2010). Despite the focus of therapy on creating phrases with the words retrieved, there were no significant differences in partner-rated functional communication and discourse. This outcome could be due to ESFA, as an impairment – based therapy not targeting communication, but only naming improvement. Though participants went beyond the single word level to producing phrases and sentences, their utterances did not have communicative intent. Promoting the use of single words acquired in therapy in genuine communication activities and specifically training on discourse tasks may be required to lead to positive changes in individuals' discourse and functional communication (Peach & Reuter, 2010; Antonucci, 2009; Falconer & Antonucci, 2012).

With regards to the changes in psychosocial and overall quality of life, the moderate to large effect sizes suggest that there is a pattern in the data that should be investigated further in future research. The differences observed in this study for the therapy group (mean difference 0.40-0.55 for psychosocial, 0.21-0.28 for overall score) exceed what has been identified as the minimal clinically important difference on the SAQOL-39g for people with aphasia (0.21) (Guo et al., 2016). This study is among the first randomized controlled studies exploring the impact of a speech and language intervention on quality of life. Strong evidence in this area comes from a German randomized controlled trial of 158 participants with aphasia, which reported gains on the SAQOL-39 following intensive speech and language therapy (Breitenstein et al., 2016). There are differences between this study and ours. The German study tested an intensive intervention (≥10 h per week), delivered over three weeks; and the intervention

comprised both linguistic-cognitive and communicative-pragmatic approaches. As this body of literature emerges, it will help us understand better what intervention components are important in aphasia therapies to lead to quality of life gains.

This study also compared ESFA therapy delivered in two different approaches-individual and combination. Findings suggested that both individual and combination participants showed therapy gains on naming, they maintained these gains and showed a generalisation effect on naming untreated words (BNT). Significant others perceived a significant change in the communication skills of their partners with aphasia and there was change in quality of life post therapy though this difference did not remain significant after adjusting for multiple comparisons.

We anticipated differences in outcomes between the two approaches. We anticipated that combination therapy participants would make greater gains in communication since they had group therapy, and individual therapy participants in naming, since individual therapy is more intensive than group therapy, where practice time is divided among the group members (Berthier & Pulvermüller, 2011). There were no significant differences in the pattern of change across time between the two groups. In terms of communication, this may be due to the nature of the treatment offered, which was the same in both the individual and the combination approaches. Participants in both approaches received a highly structured therapy, rather than the group sessions following a conversation-based approach, as is common in aphasia group therapy (Elman, 2007). This meant that participants did not have the opportunity to use their skills in real life conversations, which could have led to greater gains in communication outcomes. Nevertheless, our findings are in line with the literature. In the recent systematic review of aphasia therapies, in those studies that compared individual to group therapy, there was no difference in functional communication (Brady et al., 2016). In terms of naming, the similar outcomes in our study between the two approaches may be due to our combination participants receiving two individual therapy sessions and one group therapy session per week, i.e. two thirds of their therapy sessions or half their total amount of therapy was individual. Indeed, recent evidence suggests that a combination of individual and group therapy is more efficacious than group therapy alone (Woldag, Voigt, Bley & Hummelsheim, 2016). Still, with both naming and communication outcomes we are cautious with our interpretations as our study lacked power to detect significant differences between the approaches.

A positive finding was that naming gains generalized to untrained items for both approaches, which compares favourably to studies evaluating SFA in a group context (Antonucci, 2009; Falconer & Antonucci, 2012). It also supports Boyle's (2004) suggestion that generalisation in SFA occurs from the repeated methodical accessing of the semantic system, regardless of semantic category, as the BNT does not comprise items specifically within the semantic categories treated in our study. A further positive finding was that gains in naming were maintained at 3-month follow up. This is an important finding that adds to current knowledge on maintenance of gains after SFA. In a recent systematic review of SFA studies (Efstratiadou et al., 2018), maintenance was reported for 58.18% of participants, but most of the included studies assessed maintenance in the short term, with only 2/21 studies assessing maintenance at 3 months

or longer post therapy and only 1/4 participants in these two studies showing a positive effect (Davis & Stanton, 2005; Kristensson, Behrns & Saldert, 2015). Lastly, significant others perceived an improvement on participants' functional communicational skills at the follow-up assessment. It may be that participants need time to integrate newly acquired skills in their communication in everyday life (Kristensson, Behrns & Saldert, 2015). Or it may be that it takes time for significant others to notice changes in participants' everyday communication.

Our results need to be interpreted with caution due to the limitations of the study. Main limitations comprise: we did not manage to recruit to target; the randomization method was flawed, as participants were randomized before eligibility for speech and language therapy was checked; and the overall study tested two different therapies (mapping therapy and ESFA), with 36 participants meeting the criteria for ESFA therapy. This resulted in an uneven number of participants in the comparison groups and an underpowered study. Though small deviations from equality of the sample sizes are not detrimental (Schulz & Grimes, 2002), results of underpowered studies have to be interpreted carefully. It is uncertain whether the lack of statistical significance in the comparisons made is a true finding or a false negative. This limitation is acknowledged. Still, in our study, effect sizes were large for the main outcome measure and moderate – large for the significant secondary outcome measures. Lastly, in underpowered or not well-randomized and controlled studies, differences in outcomes could be due to differences in characteristics or other variables between participant groups. In our study, despite these limitations, no differences were found in demographics and aphasia related variables between the groups.

Strengths of the study include its controlled design, recruitment from a range of settings, and the broad eligibility criteria. Recruiting from a variety of geographic settings and from both state and private hospitals / rehabilitation centres ensured social and economic biases in participant selection were minimized. As a result, the demographic characteristics of the study sample were similar to the Greek stroke population (Vasiliadis & Zikić, 2014). In terms of eligibility criteria, in order to detect the effects of treatment in specific conditions, RCTs typically have inclusion and exclusion criteria that are quite restrictive. There is evidence that RCT populations usually don't mirror the age, gender, and race distribution of the target patient population (McKee et al., 1999; Sørensen, Lash & Rothman, 2006). In this study inclusion and exclusion criteria were broad and therefore our sample comprised people with a range of aphasia types, severities and times post-onset. The inclusion of people with severe aphasia should be noted. Unlike the current study, the majority of participants (33/55) in a recent systematic review of SFA studies were fluent and had mostly mild aphasias (Conduction and Anomic), and only 5/55 participants had severe aphasia (Efstratiadou et al., 2018). In contrast, in our study 19/38 (50%) of participants had severe aphasia. Our study, therefore, extends the evidence base of SFA therapy for aphasia to those with severe aphasia.

Another strength of the study is the use of a range of outcome measures tapping on all levels of the World Health Organisation International Classification of Functioning (WHO ICF) framework (WHO, 2001) and quality of life. This ensured key aspects of

health were considered. The goals of people with aphasia span the full spectrum of the ICF, with primary goals typically linked to the activity / participation and the body functions and structures levels (Worrall et al., 2011; Wallace et al., 2016). We also included the SAQOL-39g as a measure of quality of life, which has since been identified as a key measure of the Core Outcome Set for Aphasia (Wallace et al., 2018). Core Outcome Sets promote the use of a minimum set of outcomes in intervention studies to allow for data to be collated across studies and for comparisons between studies.

In summary, ESFA therapy led to greater improvements in naming for those in the intervention versus those in the control group. Trends were also observed for improvements in psychosocial and overall quality of life. When comparing their relative efficacy, both individual and combination ESFA led to improvements in naming, with generalization to untreated items and these gains were maintained at 3-month follow-up. Significant others perceived benefits in the communication skills of their partners with aphasia at the 3-month follow-up. Admittedly, due to the flaws in our randomization process and the smaller than intended sample size, this study has not provided level I definitive evidence on the efficacy of ESFA; it has, however, provided level II evidence. This is of significance, considering that current best practice statements for aphasia therapy for word retrieval deficits (Clinical Centre for Research Excellence in Aphasia Rehabilitation, 2014) are based on level III/IV evidence (Wisenburn & Mahoney, 2009). Additionally, the recent Cochrane review of aphasia therapy studies did not find evidence from trials of speech and language therapy vs. no speech and language therapy to support naming therapy (Brady et al., 2016). Further research is needed to confirm the reliability of the results in well-powered studies. Such studies could also allow for subgroup analysis in terms of aphasia type and severity and further inform candidacy for ESFA.

Conclusion/ clinical messages

Elaborated semantic features analysis (ESFA) can improve naming in people with different types and severities of aphasia, including those with severe aphasia. Both those who had ESFA in individual therapy and those who had a combination of individual and group therapy sessions made gains in naming and functional communication.

Author contributions

EE made a substantial contribution to the design of the work, acquisition, analysis and interpretation of data. KH made a substantial contribution to the concept and design of the work, analysis and interpretation of data. IP made a substantial contribution to the concept and design of the work. KH and EE drafted the article. SV, IP and RH revised the article critically for important intellectual content. All authors approved the version to be published and take public responsibility for appropriate portions of the content.

Declaration of conflicting interests

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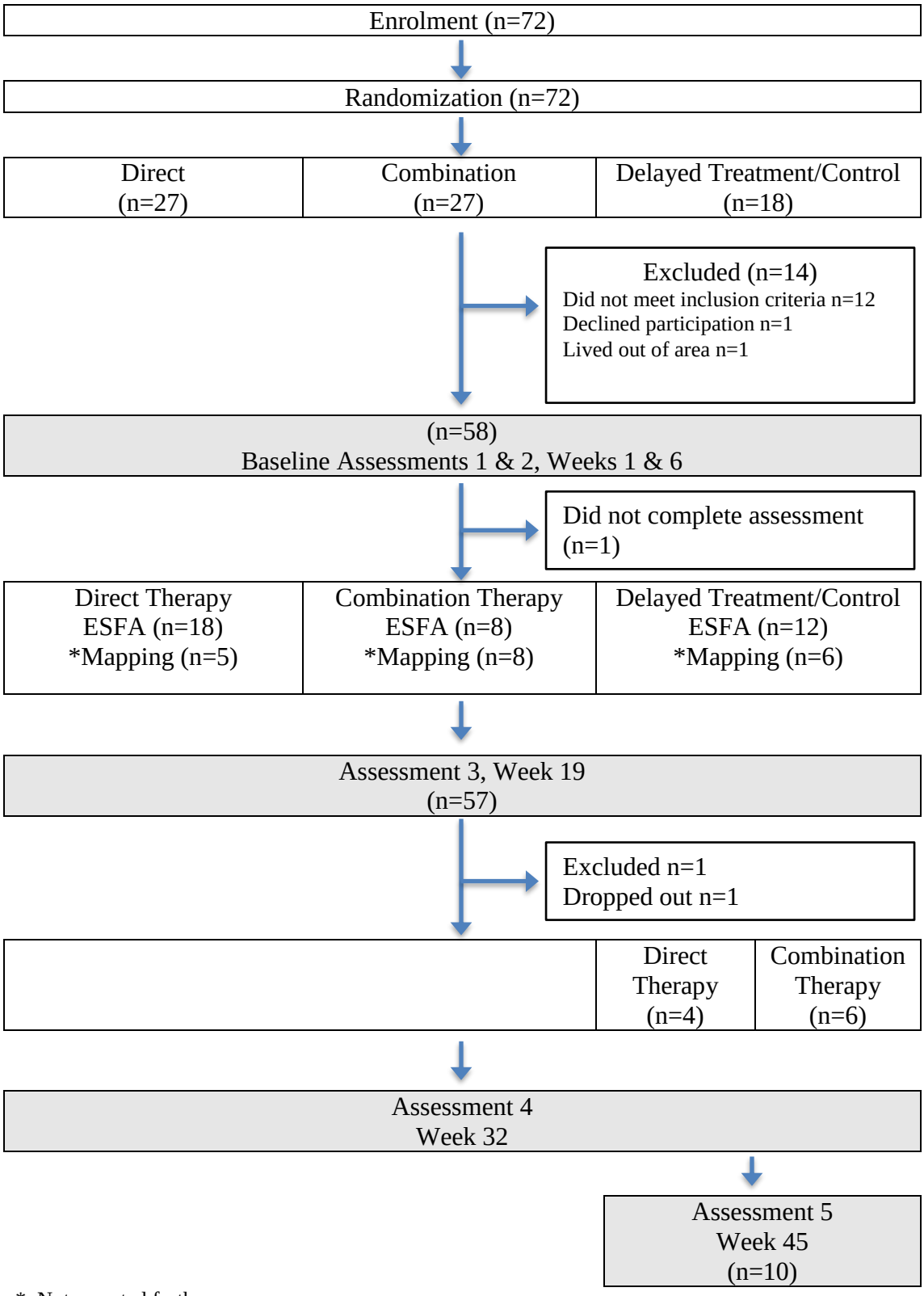
Figure 1: CONSORT diagram of participant flow in the study



*: Not reported further

Table 1: Participant characteristics of therapy group (n=26) and control/ delayed therapy group (n=12)

Variables	Therapy Group (n=26)	Control / Delayed Therapy Group (n= 12)
Age (years)		
Mean (SD)	58.38 (11.26)	58.42 (11.99)
Range	38 – 84	44 - 79
Gender		
Male	20	6
Female	6	6
Time Post Onset (months)		
Mean (SD)	36.73 (49.30)	16.00 (21.89)
Range	4 - 207	4 - 78
Work Status		
Full – time	11	6
Part – time	1	1
Self-employed	4	1
Unemployed	-	1
Retired due to age	8	3
Retired due to disability	2	-
Marital Status		
Single	2	2
Married	17	6
Divorced	5	2
Widowed	2	2
Education Status (years)		
Mean (SD)	13.27 (3.80)	13.00 (4.45)
Range	6 - 20	6 - 21
Type of Stroke		
Haemorrhagic	-	1
Ischaemic	26	11
Aphasia Type (based on BDAE)		
Broca's	9	5
Wernicke's	1	-
Anomic	5	1
Global	7	3
Conduction	-	2
Unclassified	4	1
Aphasia Severity (BDAE)		
Mild	5	3
Moderate	7	4
Severe	14	5
Fluency Status (BDAE)		
Fluent	5	5
Non Fluent	21	7

Table 2: Therapy (n=26) and control group (n=12) scores on outcome measures across time

		Mean (SD) scores			Time effect		Interaction effect	
Measure	**Group**	**BL1**	**BL2**	**Post therapy/BL3**	**p**	**η^2_p (90% CIs)**	**p**	**η^2_p (90% CIs)**
S & V	Control	67.83 (57.29)	74.33 (62.94)	81.83 (69.90)	<.001	.42	.003	.21
	Therapy	56.15 (45.74)	61.96 (49.50)	104.38 (73.91)		(.22 - .56)		(.05 - .37)
BNT	Control	7.75 (5.45)	8.92 (6.87)	10 (8.37)	.002	0.19	ns	.04
	Therapy	6.85 (7.17)	6.81 (6.53)	9.84 (9.29)		(.05 - .33)		(.00 - .14)
ASHA-FACS	Control	4.91 (1.19)	5.13 (1.13)	5.28 (1.09)	ns	0.12	ns	.01
	Therapy	5.24 (1.09)	5.24 (1.13)	5.55 (.92)		(.01 - .25)		(.00 - .08)
Discourse	Control	17.65 (24.47)	19.16 (23.81)	18.64 (22.47)	ns	.01	ns	.02
	Therapy	16.35 (24.62)	15.22 (23.11)	18.14 (30.04)		(.00 -.08)		(.00 - .10)
GHQ-12	Control	6.00 (2.41)	5.50 (2.39)	6.17 (2.17)	ns	.01	ns	.01
	Therapy	6.27 (1.93)	6.04 (2.44)	6.12 (1.66)		(.00 - .07)		(.00 - .05)
SAQOL-39g								
Physical	Control	3.31 (1.02)	3.20 (1.12)	3.17 (.95)	ns	.01	ns	.03
	Therapy	3.80 (1.01)	3.79 (.98)	3.89 (.92)		(.00 - .05)		(.00 - .10)
Psychosocial	Control	2.75 (.78)	2.95 (.77)	2.63 (.82)	ns	.01	p= .013	.12
	Therapy	3.07 (1.04)	2.92 (.98)	3.47(.93)		(.00 - .08)		(.02 - .24)
Communication	Control	2.52 (.78)	2.83 (1.07)	2.65 (1.18)	ns	.04	ns	.03
	Therapy	2.77 (.90)	2.82 (.90)	2.86 (.91)		(.00 - .14)		(.00 - .11)
Overall	Control	2.94 (.60)	3.01 (.69)	2.83 (.54)	ns	.01	p= .015	.11
	Therapy	3.31 (.75)	3.24 (.73)	3.52 (.72)		(.00 - .05)		(.01 - .22)
EQ-5D	Control	60.83 (23.53)	55.42 (20.61)	50.83(15.20)	ns	.01	ns	.08
	Therapy	63.54 (19.35)	67.12 (16.62)	69.12(15.59)		(.00 - .04)		(.00 - .18)

ASHA-FACS: American Speech and Hearing Association Functional Assessment of Communication Skills; BL: baseline; BNT: Boston Naming Test; CIs: Confidence Intervals; GHQ-12: General Health Questionnaire – 12 item version; ns: not significant; SAQOL-39g: Stoke and Aphasia Quality of Life Scale- 39 item generic stroke version; SD: Standard Deviation; S &V: Snodgrass and Vanderwart naming measure.

Table 3: Individual therapy (n=22) and combination therapy (n=14) group scores on outcome measures across time

		Mean (SD) scores				Time effect		Interaction effect	
Measure	**Therapy group**	**BL1**	**BL2**	**Post therapy**	**Follow up**	**p**	**η^2_p (90% CIs)**	**p**	**η^2_p (90% CIs)**
S & V	Individual	58.91 (50.14)	66.23 (53.95)	103.64 (77.01)	96.32 (68.49)	p< .001	.49	ns	.01
	Combination	62.14 (49.67)	75.29 (62.64)	116.79 (79.45)	111.64 (76.90)		(.33 - .59)		(.00 - .06)
BNT	Individual	6.95 (6.74)	7.41 (7.22)	10.77 (10.80)	10.32 (10.27)	p< .001	.29	ns	.01
	Combination	7.50 (6.98)	8.00 (6.21)	13.14 (10.28)	11.21 (10.14)		(.13 - .41)		(.00 - .07)
ASHA-FACS	Individual	5.21 (1.12)	5.30 (1.08)	5.55 (.94)	6.02 (.73)	p= .001	.18	ns	.03
	Combination	5.11 (1.13)	5.15 (1.20)	5.44 (.97)	5.47 (1.18)		(.05 - .29)		(.00 - .10)
Discourse	Individual	16.18 (25.03)	14.74 (24.73)	17.43 (31.03)	17.93 (27.80)	ns	.03	ns	.01
	Combination	17.45 (21.87)	16.63 (18.15)	18.23 (21.48)	17.13 (21.71)		(.00 - .08)		(.00 - .04)
GHQ-12	Individual	6.32 (1.91)	5.91 (2.39)	6.00 (1.72)	5.86 (1.67)	ns	.01	ns	.02
	Combination	5.50 (1.99)	5.50 (2.50)	5.21 (2.19)	6.00 (1.75)		(.00 - .04)		(.00 - .06)
SAQOL-39g									
Physical	Individual	3.62 (1.05)	3.64 (1.07)	3.82 (.91)	3.66 (1.07)	ns	.05	ns	.01
	Combination	3.91 (.87)	3.74 (.98)	3.98 (.85)	3.86 (1.06)		(.00 - .12)		(.00 - .04)
Psychosocial	Individual	2.87 (1.02)	2.91 (1.05)	3.08 (1.10)	3.32 (.92)	ns	.07	ns	.03
	Combination	3.18 (.94)	3.01 (.73)	3.53 (.70)	3.26 (.83)		(.00 - .15)		(.00 - .09)
Communication	Individual	2.60 (.90)	2.68 (.98)	2.71 (.97)	2.78 (.95)	ns	.05	ns	.01
	Combination	2.92 (.79)	3.03 (.76)	3.12 (.94)	3.26 (1.15)		(.00 - .13)		(.00 - .03)
Overall	Individual	3.13 (.75)	3.15 (.79)	3.31 (.78)	3.35 (.78)	p= .046	.09	ns	.02
	Combination	3.43 (.60)	3.28 (.61)	3.62 (.57)	3.49 (.73)		(.001 - .18)		(.00 - .07)
EQ-5D	Individual	63.73 (18.37)	63.41 (18.86)	67.14 (17.06)	66.82 (13.23)	ns	.07	ns	.02
	Combination	59.29 (25.26)	63.57 (19.46)	68.21 (17.05)	70.71 (14.53)		(.00 - .14)		(.00 - .06)

ASHA-FACS: American Speech and Hearing Association Functional Assessment of Communication Skills; BL: baseline; BNT: Boston Naming Test; GHQ-12: General Health Questionnaire – 12 item version; ns: not significant; SAQOL-39g: Stoke and Aphasia Quality of Life Scale- 39 item generic stroke version; S &V: Snodgrass and Vanderwart naming measure.

Figure 2: Interaction effects for therapy (n=26) versus control group (n=12) across time for S&V, BNT, ASHA-FACS, Discourse, GHQ-12, EQ-5D, and SAQOL-39 overall and psychosocial

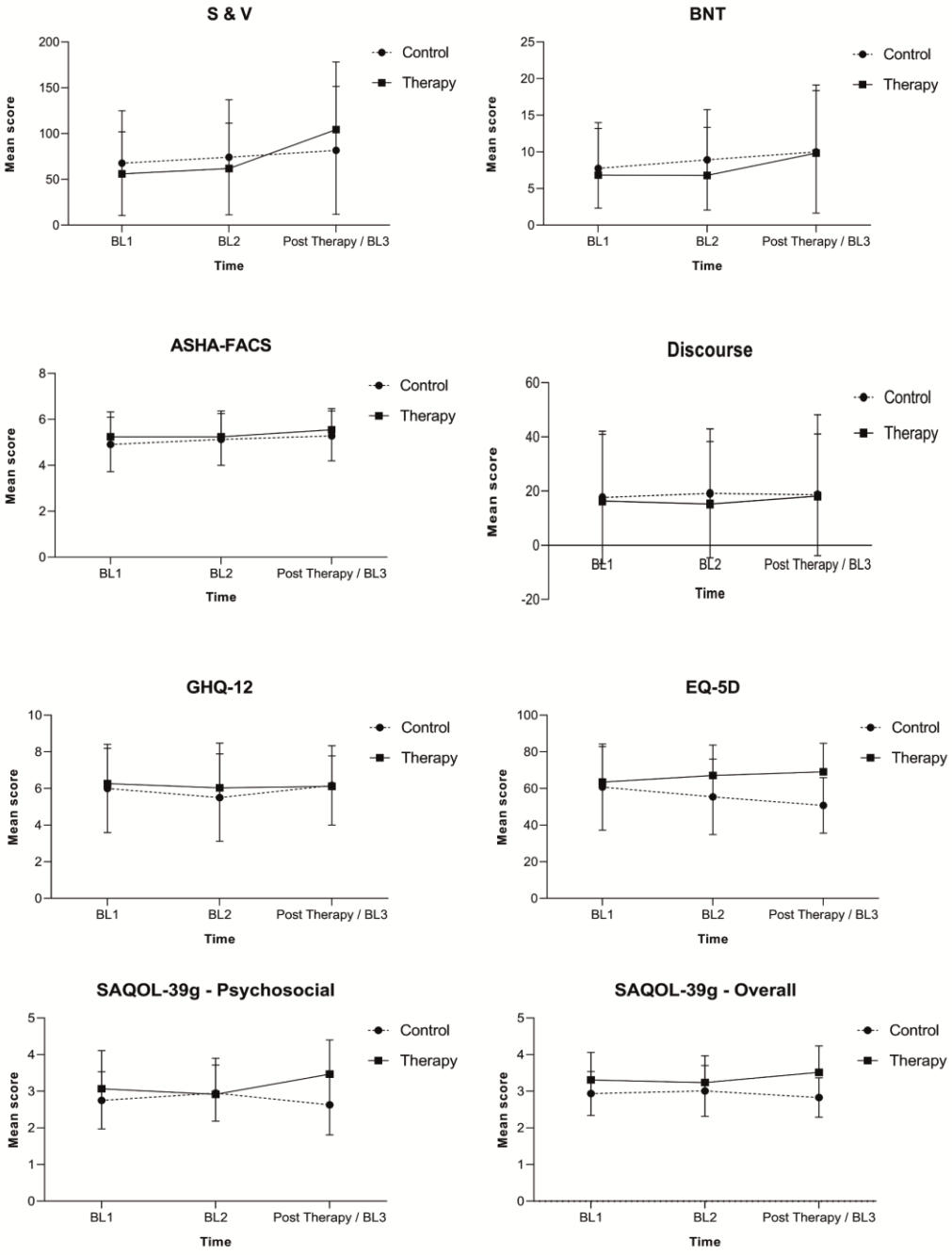


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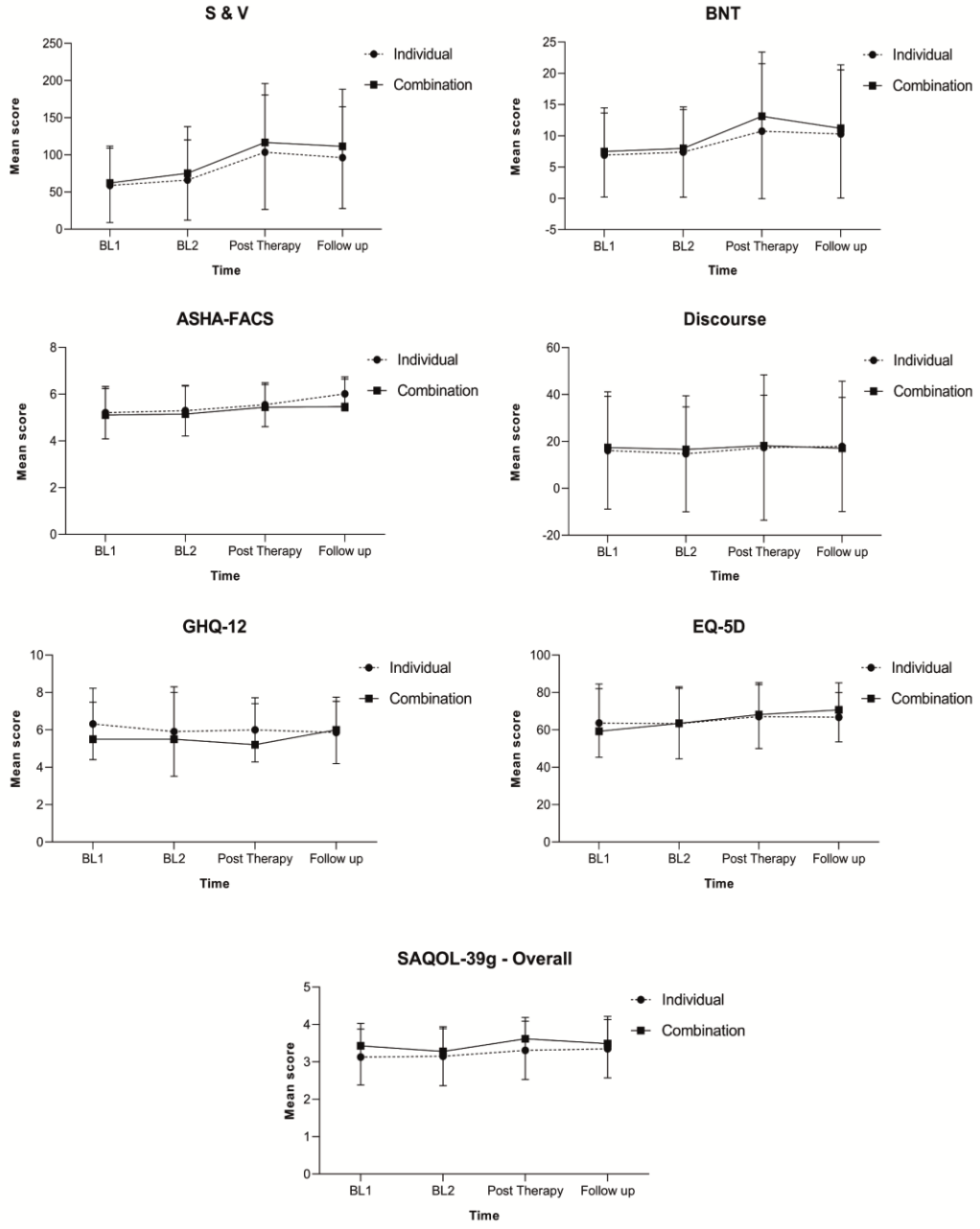
Figure 3: Interaction effects for individual therapy (n=22) versus combination therapy (n=14) across time for S&V, BNT, ASHA-FACS, Discourse, GHQ-12, EQ-5D, and SAQOL-39 overall.



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