

Abstract

Background: Communication outcomes following stroke are improved when treatments for aphasia are administered early, within the first 3 months after stroke, and provided for more than two hours per week. However, uncertainty remains about the optimal type of aphasia therapy.

Aims: We compared Constraint Induced Aphasia Therapy (CIAT) with individual, impairment-based intervention, both administered early and daily after acute stroke.

Materials and Procedures: This prospective, single-blinded, randomised, controlled trial recruited participants with mild to severe aphasia within ten days of an acute stroke from acute/subacute Perth metropolitan hospitals (n=20). Participants were allocated by computer generated block randomisation method to either the CIAT (n= 12) or individual, impairment based intervention group (n= 8) delivered at the same intensity (45-60 minutes, five days a week) for 20 sessions over five weeks (15-20 hours total). The primary outcome, measured after completing the intervention, was the Aphasia Quotient (AQ) from the Western Aphasia Battery. Secondary outcomes were the AQ at 12 and 26 weeks post stroke, a Discourse Analysis (DA) score and the Stroke and Aphasia Quality of Life Scale (SAQoL), measured at therapy completion, 12 and 26 weeks post stroke. There was a 10% (n= 2) dropout at the primary endpoint, both participants were in the CIAT group. The estimates for each treatment group were compared using repeated measures ANOVAs. Data from the 26 week follow-up assessment is presented however was not included in the between-group comparisons due to the low number of data points in each group.

Outcomes & Results: Within groups analyses comparing performance at baseline, therapy completion and 12 weeks post stroke revealed a statistically significant treatment effect for the AQ ($p < .001$), DA ($p = .002$) and SAQoL ($p < .001$). Between groups analysis found there was no significant difference between the CIAT and individual therapy groups on any outcome measure.

Conclusions: CIAT and individual therapy produced comparable amounts of change in the very early phase of recovery suggesting a standard, intensive daily dose of therapy within this period of recovery is feasible and beneficial. There were no significant differences between the two groups demonstrating that CIAT, which is provided in a group format, may be a viable option in the very early phase of aphasia recovery. The study highlights the need for further research into the impact of therapy type in very early aphasia therapy.

Key words: aphasia; Constraint Induced Aphasia Therapy; very early rehabilitation

Introduction

Treatment for aphasia shows some benefit (Brady, Kelly, Godwin & Enderby, 2012). Evidence indicates communication outcomes are improved when therapy is commenced within the first three months post stroke, and when therapy is provided for more than two hours per week for an extended period of time (Bhogal, Teasell & Speechley, 2003). Commencing aphasia rehabilitation in the very early recovery phase (within the first 14 days post stroke) is thought to enhance communication outcomes by strengthening existing neural networks following brain injury (Kreisel, Hennerici & Bazner, 2007), optimising neural plasticity in order to facilitate the restoration of damaged neural pathways (Murphy & Corbett, 2009). Delay in commencing therapy after stroke may lead to the development of maladaptive compensatory behaviours that have a negative impact on functional outcomes (Murphy & Corbett, 2009). Commencing aphasia therapy very early has led to greater communication outcomes at 6 months when compared to a usual care control cohort (Godecke et al., 2014; Godecke, Hird, Lalor, Rai & Phillips, 2012). The treatment provided in these papers and in the majority of other studies commencing intervention in early recovery was predominantly provided on an individual basis (see for example Bowen et al., 2012; Godecke et al., 2012; Laska, Kahan, Hellbloom, Murray & von Arbin, 2011). The specific therapeutic regimen that is most effective in facilitating recovery remains unclear.

Constraint Induced Aphasia Therapy (CIAT)

Constraint Induced Aphasia Therapy (CIAT) also known as Constraint Induced Language Therapy (CILT) has received extensive research attention. This therapy is based on principles of Constraint Induced Movement Therapy (see for example Taub, Uswatte & Pidikiti, 1999) and is an example of an Intensive Language Action Therapy (Difrancesco, Pulvermuller & Mohr, 2012). This approach to treatment incorporates principles of neuroplasticity such as providing therapy in an intensive manner through the provision of

massed practice. Additionally, CIAT involves a pragmatically communicative therapeutic context, in which people with aphasia (PWA) are required to use spoken language, rather than alternative forms of communication such as gesture, writing and communicative aids. Individuals engage in request dialogues in a small group context where specific items are requested and appropriate responses made. Pulvermuller et al. (2001) hypothesised communicative effectiveness is increased and learned non-use of expressive language minimised. The target material is designed to shape each individual's language production, with rules and reinforcement contingencies used to extend expressive output. Pulvermuller and Berthier (2008) and Difrancesco et al., (2012) provide extensive descriptions of the neuroscientific principles underlying the treatment approach.

Pulvermuller et al.'s (2001) original study, investigating the effectiveness of CIAT in comparison to 'conventional therapy', involved 17 PWA in the chronic stage of aphasia recovery. Participants were randomly allocated to either a CIAT group, receiving 30 hours of therapy over a period of 10 days, or a one-on-one conventional therapy cohort, in which the same total amount of therapy was provided over a longer period of time (approximately four weeks). This initial study found the participants in the CIAT group made greater gains on assessments of communication after therapy. However it is not clear whether this result was due to the intensive nature of the treatment provided to the CIAT group or the nature of the CIAT task itself.

Since Pulvermuller et al., (2001), studies have further investigated the use of CIAT in the chronic stage of aphasia recovery post stroke. In a 2008 systematic review Cherney, Patterson, Raymer, Frymark and Schooling noted the positive effects of CIAT but concluded the impact of treatment intensity is multifaceted and may depend on the type of treatment administered, the phase of recovery and the type of aphasia being treated. In an updated systematic review Cherney, Patterson and Raymer (2010) examined 26 studies from both

the chronic (≥ 6 months post onset), subacute (≤ 3 months post onset) and acute (≤ 1 month post onset) phases of aphasia recovery. Of the 26 studies, eight addressed the question of treatment intensity, 17 investigated CIAT and one addressed both treatment intensity and CIAT. Cherney et al., (2010) found treatment benefits in implementing CIAT however they noted due caution was required when interpreting this finding given the exploratory nature of the majority of studies, including small sample sizes and lack of description regarding the intervention, and called for further research to establish the efficacy of CIAT.

The timing of CIAT therapy post stroke

The majority of studies have investigated the effect of CIAT on participants in the chronic phase of recovery. Only three studies (Kirmess & Lind, 2011; Kirmess & Maher, 2010 & Sickert, Ander, Münte & Sailer, 2014) have examined the impact of therapy commencing in the acute or subacute phase. Sickert et al. (2014) conducted a randomised, single-blind, parallel group study comparing the effectiveness of CIAT (n=50) to standard aphasia therapy (n=50). Therapy was commenced an average of 34.8 (28-112) days post stroke with outcomes measured immediately post, 8 weeks and 1 year after intervention. All therapy was administered in small groups of 4 - 6 participants for two hours per day for 15 days. Both groups demonstrated significant change in all measures immediately post treatment with no group differences observed. These gains were maintained at the 8 week and 1 year follow up time points.

Utilising a single case design Kirmess and Maher (2010) (n= 3) and Kirmess and Lind (2011) (n= 3) investigated the effectiveness of providing CIAT when therapy was commenced an average of 46.6 (40- 58) days (Kirmess & Maher, 2010) and 56 (28- 98) days post stroke (Kirmess and Lind, 2011). Outcomes were measured at 3 and 6 months post intervention (Kirmess & Maher, 2010) and immediately post intervention (Kirmess & Lind, 2011). One participant was involved in both studies. Participants completed up to 3 hours of therapy per **day** over the 10 day treatment period. All participants demonstrated an

overall pre- post improvement on a range of language tests, including a range of discourse measures (Kirmess & Lind, 2011) with a greater change noted for expressive than receptive tasks. Kirmess and Maher (2010) found continued improvement on most measures at follow-up.

In research outlined above (Kirmess & Lind, 2011; Kirmess & Maher, 2010 & Sickert et al., 2014) CIAT resulted in improved language functioning when therapy was commenced during the subacute phase of recovery post stroke, however further research is needed to validate these findings. Participants in the Sickert et al., (2014) study were recruited across a wide period of time post stroke, which may have influenced participants' response to therapy. The Kirmess and Maher (2010) and Kirmess & Lind (2011) studies included a low number of participants across the two studies and did not include a comparison treatment group. Furthermore studies are yet to investigate the effectiveness of CIAT commenced in the very early phase of aphasia recovery. The use of this treatment approach may be beneficial when commenced within 14 days of stroke onset when natural brain recovery is thought to be at its optimal level. Greater knowledge regarding the effectiveness of treatments, including CIAT, provided during the very early and acute phases of recovery is required in order to develop an understanding of specific therapeutic regimens that are most effective in facilitating recovery. This project aimed to compare CIAT and individual, impairment focused aphasia therapy started within the first 14 days following acute stroke, in order to investigate the impact of treatment type on the communication outcomes of individuals with post stroke aphasia.

Methods

Design

A prospective, single blinded, randomised controlled trial was conducted, with participants randomly assigned (see below) to CIAT group therapy or to individual, impairment based aphasia therapy. The primary endpoint was at therapy completion which was a maximum of

50 days post stroke. Ethical approval was obtained from the recruiting hospitals prior to commencing the study. Data from this study was published previously in Godecke et al. (2013 & 2014) however in the previous studies the data from both groups was pooled and compared to a group of usual care participants from Godecke et al. (2012). In Godecke et al. (2013) the data from both groups was also combined with data from the treatment arm of the Godecke et al. (2012) study. The analysis of data for this study which compares the effect of CIAT and individual, impairment based therapy has not previously been published.

Setting

Participants were recruited from Royal Perth Hospital (RPH) or Sir Charles Gairdner Hospital (SCGH) in Perth, Western Australia, between December 2008 and September 2009. Both facilities are large, metropolitan teaching hospitals with over 400 stroke admissions per year. Therapy was initiated at the admitting site and then continued at the corresponding rehabilitation facility; either RPH - Shenton Park Rehabilitation Unit or Osborne Park Stroke Rehabilitation Unit (OPH). The prescribed treatment, as started in the acute hospital, was continued in the rehabilitation units without interruption.

Participant Recruitment

Participants were identified from the hospital-generated daily admissions list from each participating hospital. Medical notes were screened for all admissions with a diagnosis of stroke, falls, headache, confusion and seizures on the day of admission or on the next working day. Individuals with a possible or confirmed stroke were identified as potential participants.

Inclusion criteria

The following criteria were applied: 1) acute stroke diagnosed by a neurologist or stroke physician and confirmed by computer tomography and/ or magnetic resonance imaging

within 48 hours of hospital admission, 2) aphasia as diagnosed by a score of less than 13/20 on the shortened Frenchay Aphasia Screening Test (FAST) (Enderby, Wood & Wade, 1987) and aphasia severity score of less than 93.7 on the Aphasia Quotient (AQ) of the Western Aphasia Battery (WAB; Kertesz, 1982), 3) a moderate level of alertness as measured by a Glasgow coma scale of >10 (Teasdale & Jennett, 1974), 4) the ability to maintain sufficient alertness to interact in therapy for at least 30 consecutive minutes. The exclusion criteria were: 1) a documented previous diagnosis of aphasia, head injury, neurodegenerative disease or mental illness, 2) a previous medical history of sub-arachnoid and/ or sub-dural haemorrhage or neurosurgical intervention, 3) uncorrected hearing or vision impairment and 4) inability to participate in English based therapy due to English being a second language.

All participants were consented, recruited, randomised and assessed within 10 days of stroke onset and commenced treatment within 11 days of stroke onset.

Baseline Data

Participant characteristics including demographic factors, stroke features, stroke classification according to Oxfordshire Community Stroke Project Classification (Bamford, Sandercock, Dennis, Burn and Warlow, 1991), the modified Rankin Scale (mRS) (Rankin, 1957), the AQ (WAB) were collected at baseline and are shown in Table 1.

Please insert Table 1 about here

Therapist training

A total of eight qualified speech and language pathologists provided the intervention.

Therapists ranged in experience from 1-23 years. All therapists provided either individual therapy or CIAT as per study protocol manuals. Therapists undertook three hours of therapy training prior to providing therapy to the participants.

Intervention

Participants were randomly allocated by a computer generated block randomisation method with sealed envelopes controlled by administrative staff (external to the trial) to either the individual (n= 8) or the CIAT (n= 12) intervention group. The prescribed amount of therapy for both groups was 45 - 60 minutes per day of direct aphasia therapy for a total of 20 sessions which were completed over a period of 4 - 5 weeks. This equated to a minimum of 15 and a maximum of 20 hours completed during the 20 sessions which were completed before day 50 post stroke. Therapists manually recorded the number of minutes in direct aphasia therapy for the duration of the intervention period. This information was then entered into the trial database by research assistants. Additionally, therapists were required to record all usual care services to all participants in the Allied Health System (AHS), which is a health system database. Manually recorded data and data from the AHS were cross-referenced and showed 100% agreement in aphasia therapy intervention sessions for therapy dates, session duration, and type of therapy provided.

Constraint Induced Aphasia Therapy

Therapy was based on CIAT as outlined by Pulvermuller et al. (2001) and Pulvermuller et al. (2008). Due to the early nature of the intervention, therapy was modified from the original 3 hours per day to 1 hour per day. This amount of daily therapy has been shown to be feasible and tolerated by people with aphasia in the very early phase of recovery (Godecke et al., 2012). Therapy was conducted by one speech and language pathologist with groups of 2-4 people with varying levels of aphasia severity. The group was composed of study participants and clients from the concurrent speech pathology caseload for whom intensive language therapy was an appropriate option. This was done to ensure there was always a group available for research participants.

The therapy task of CIAT was a request and response language activity in which participants aimed to collect the highest number of paired picture cards. Participants were constrained to interact through verbal production only. Sitting around a table, each participant had a visual barrier preventing them from seeing the cards of other group members, while allowing them to see and hear each other. Shielded by the barrier, participants could use self-cued gesture to facilitate their verbal production. Participants took turns to try to obtain a card from another player by verbally requesting a card. Each request prompted a verbal response such as confirmation, clarification or negation.

The coloured picture stimuli within each set of cards accommodated a verbal response ranging from single words to sentences. Increased target description, extended phrasal and clausal structures and politeness markers were encouraged to achieve increased utterance complexity and appropriateness according to each player's ability. For example adjectives were added to increase the level of description and expand noun phrases, subject verb combinations and the inclusion of a carrier phrase 'do you have a...' were elicited to increase the complexity of the utterances produced and politeness markers such as using the individual's name or saying 'please' as part of the request were used as appropriate. The therapist provided language support as required to each player according to their individual needs. This was established at initial assessment and monitored and adjusted in response to the individual's performance within the treatment sessions. See Appendix A for the treatment protocol which includes examples of stimuli used and the support provided to participants.

Individual therapy

Participants in this therapy arm received an individualised program tailored to meet their needs. The treatments were selected from the impairment based therapies used at the treating sites. Using the individual's initial assessment results to inform their decision making, the treating therapist selected the appropriate therapeutic approach from the

following: Semantic Feature Therapy (Boyle & Coelho, 1995), Cued Naming Therapy (Nettleton & Lesser, 1991), Lexical Semantic (BOX) Therapy (Visch-Brink, Bajema & Vande Sandt-Koenderman, 1997), Mapping Therapy (Schwartz, Saffran, Fink, Myers & Martin, 1994) and Phonological Feature Mapping (Raymer, Thompson, Jacobs & LeGrand, 1993). The therapies were administered following the respective published instructions. The treatments were used to elicit single words and then these words were produced in the context of a multiword utterance, the complexity of the utterance being guided by the individual's language ability. All participants received Cued Naming Therapy in combination with one of the other therapies depending on the severity of the individual's aphasia and at the clinical discretion of the treating clinician. Those with milder aphasia (AQ 62.6- 93.6) generally received Cued Naming in conjunction with Box Therapy and Mapping Therapy, participants with moderate aphasia (AQ 31.3- 62.5) received Cued Naming, Semantic Feature Therapy and Phonological Feature Mapping and individuals with severe aphasia (AQ 0- 31.2) received Cued Naming Therapy and Semantic Feature Therapy. The treating therapist monitored each participant and therapy progressed through the treatment hierarchies accordingly.

Outcome measurement

Participants were assessed on entry into the study, immediately following therapy completion and at follow up at 12 and 26 weeks post stroke. All assessments were conducted and analysed by a trained assessor who was blinded to group allocation and was not involved in the provision of therapy.

Primary Outcome Measure

The primary outcome measures was the AQ from the WAB (Kertesz, 1982) at therapy completion. The WAB is a standardised aphasia battery in which the AQ is derived from

language subtests involving spontaneous speech, auditory verbal comprehension, word repetition and naming tasks.

Secondary Outcome Measures

The secondary outcome measures were:

- The AQ (Kertesz, 1982) score at 12 weeks post stroke.
- Discourse Analysis (DA) score (Godecke et al., 2013) at therapy completion and 12 weeks post stroke. DA is the % Correct Information Units (Nicholas & Brookshire, 1993) produced per minute (%CIU/ min) and reflects both communicative accuracy and efficiency (Godecke et al., 2012). The discourse samples were elicited through the description of a single picture and production of personal and procedural narratives (Nicholas & Brookshire, 1993). A count of 200 or more intelligible words across the samples was required for the analysis to be completed. If a participant could not produce 200 or more intelligible words, a '0' score was assigned (Godecke et al., 2013). All samples were audio recorded, transcribed verbatim and then analysed by the blinded assessor following the CIU procedures as outlined in Nicholas and Brookshire (1993). Five percent of the samples were scored by a second analyst with 96% inter-rater agreement.
- The Stroke and Aphasia Quality of Life Scale (SAQoL) (Hilari et al., 2003) at therapy completion and 12 weeks. The SAQoL is an interview administered, self-report scale that reflects the impact of stroke and aphasia on the individual's quality of life (Hilari et al., 2003).

Statistical Analyses

The CIAT and individual treatment groups were compared at baseline using two-tailed t-tests and chi-square test for independence. Pre, post-intervention and follow up comparisons in the outcome measures were undertaken using a split plot ANOVA to assess

differences between the CIAT and individual treatment groups at therapy completion and 12 weeks post stroke. A significance level of .05 (two-tailed) was used. Effect sizes were calculated using partial eta squares. In keeping with the intention to treat principle, all participants were analysed in the groups to which they were randomised. No attempt was made to impute missing data for patients who were lost to follow-up.

Results

Baseline

Over the 10 month recruitment period the medical notes for 1006 admissions to RPH were screened for collapse, falls, seizures, headache, confusion and stroke. Of these, a total of 236 people were admitted with an acute stroke with 88 (37.3%) having confirmed aphasia. Thirty-five of these people met the study criteria. Of the 53 patients not meeting the inclusion criteria, 21 (39.6%) had previous aphasia and/or dementia, 13 (24.5%) were receiving palliative care, 10 (18.9%) were too drowsy to participate and 9 (17%) were excluded for other reasons. Fifteen (42.8%) of the 35 patients who met the selection criteria, were not recruited. Of these, 12 (80%) had an AQ score 93.7 or above and 3 (20%) refused. Eighteen individuals with aphasia were recruited to the study from RPH. An additional two participants met the selection criteria and were recruited from SCGH. See Figure 1.

Please insert Figure 1 about here

Twelve participants were allocated to the CIAT and eight were allocated to individual therapy. Apart from stroke classification (Oxfordshire; Bamford, 1991), the baseline characteristics of participants in the CIAT and individual therapy groups were not significantly different. Table 1 shows the baseline characteristics and comparisons for the CIAT and individual therapy groups.

Intervention Compliance

Following baseline assessment two (10%) of the CIAT group did not reach the minimum intervention requirement due to medical complications and withdrew from the study. Of these, one participant suffered a further stroke after completing a single 40- minute therapy session and the second suffered a gastric haemorrhage after completing 13 sessions and 13 hours of therapy. Overall, participants received an average of 18.35 (1-20) therapy sessions provided over a mean of 38.5 (1-49) days post stroke. Figure 1 outlines the progress of participants through the study. Table 2 outlines group and overall intervention time received by all participants.

Please insert Table 2 about here

Longitudinal Changes and Group Comparisons

Table 3 contains grouped results for all participants recruited to the study. Due to the small number of participants who completed the 26 week assessments, statistical comparisons were only made at three time points (pre-treatment, post-treatment and the 12 week follow up). All outcomes were assessed using a split plot ANOVA. For all measures a significant change was noted over time. However there were no significant group effects.

Please insert Table 3 about here

Participants from both groups showed significant improvement over time on the WAB-AQ ($p < .001$) (see Figure 2). Post-hoc pairwise longitudinal comparisons were performed with a Sidak adjustment applied to the p-values. The Sidak adjustment (Šidák, 1967) provides the exact value of the upper bound for the probability of the Type I error in the case of multiple comparisons. It is preferred to the older and more popular Bonferroni adjustment

(Bonferroni, 1936) which provides an approximation of the same error bound. These comparisons indicated that participants showed a 24-point improvement from baseline at therapy completion ($p = .005$). At follow up, the change from baseline had increased to 30 points ($p < .001$), however the 6-point change from therapy completion to follow up was not statistically significant ($p = .051$). The interaction effect for between group comparison over time was not significant ($p = .953$). The effect size for the longitudinal comparison was 0.742 (large), for the between groups comparison was 0.008 (small) and for the interaction effect was 0.001 (small).

Please insert Figure 2 about here

On the DA measure participants from both groups showed significant improvement over time ($p = .002$) (see figure 3). Post-hoc pairwise longitudinal comparisons were performed with a Sidak adjustment was applied to the p-values. These comparisons indicated that participants showed a 6.4-point improvement from baseline at therapy completion. However, this difference was not statistically significant ($p = .083$). At follow up, the change from baseline had increased to a statistically significant 9.1 points ($p = .011$) This represents a clinically significant change with participants able to produce significantly more accurate and efficient verbal output. The 2.7-point change from therapy completion to follow up being non-significant ($p = .279$). The interaction effect for between group comparison over time was not significant ($p = .185$). The effect size for the longitudinal comparison was 0.389 (large), for the between groups comparison was 0.002 (small) and for the interaction effect was 0.122 (medium- large).

Please insert Figure 3 about here

Results of the SAQoL showed a significant improvement in scores for participants from both groups ($p < .001$) (see Figure 4). Post-hoc pairwise longitudinal comparisons were performed with a Sidak adjustment applied to the p-values. These comparisons indicated that participants showed a 1.79-point improvement from baseline at therapy completion ($p = .003$). At follow up, the change from baseline had increased to a statistically significant 1.89 points ($p = .001$) with the 0.1-point change from therapy completion to follow up being non-significant ($p = .898$). The interaction effect for between group comparison over time was not significant ($p = .668$). The effect size for the longitudinal comparison was 0.649 (large), for the between groups comparison was 0.002 (small) and for the interaction effect was 0.026 (small-medium).

Please insert Figure 4 about here

Discussion

This study compared CIAT and individual, impairment based therapy provided during the very early phase of aphasia recovery. The results have implications for the provision of therapy during this phase of aphasia recovery both in relation to models of service delivery and the timing of therapy commencement.

Therapy effectiveness

The participants made significant gains across the intervention period. Positive change was noted between the baseline and post intervention assessment (AQ and SAQoL) and between baseline and 12 week follow up assessment (DA). The positive changes noted on the AQ and SAQoL were maintained at follow up. The changes noted in this study are reflected in the large effect sizes noted for all outcome measures over time. The changes indicate that substantial improvement was made regardless of group allocation. This suggests both therapies led to an improvement in outcomes for the individuals involved in

the study. The small between-group effect sizes indicate that there was no meaningful difference between the groups on any outcome measure. Additionally the small effect size for interaction between group and time for AQ and SAQoL indicates that the trajectory of improvement on these measures (over time) was similar for both groups. The medium- large effect size for interaction between group and time on the DA measure suggests the pattern of improvement, on this measure, was different between the two groups. Although the between groups comparison was not statistically significant the individuals in the CIAT group demonstrated a greater degree of improvement at therapy completion.

Given the timing of intervention, spontaneous recovery is expected to have had an impact on these findings. To account for the impact of spontaneous recovery the amount of change, shown by participants in this study, can be compared to that demonstrated by the usual care cohort in Godecke et al. (2012). The majority (23/27) of the usual care cohort did not receive any therapy and those who did, received an average of 11 minutes of therapy per week for three weeks (Godecke et al., 2012). On the AQ, the usual care cohort demonstrated an 11 point change between baseline line and therapy completion, in comparison to a 24 point change in the current study. On the DA measure the usual care cohort had a 1.2 point change between baseline and therapy completion in comparison to the 6.4 point change demonstrated in this study (Godecke, 2014). The SAQoL was not completed within the Godecke et al. (2012) study. In both instances the individuals in the current study demonstrated a greater degree of change suggesting treatment, and not just spontaneous recovery, had an impact on the language abilities of these participants.

These results indicate participants from both groups made significant gains on a range of outcome measures, namely a standardised test for expressive and receptive language skills, the efficiency with which discourse was produced and within the area of health related quality of life. These results support the findings of Kirmess and Maher (2010), Kirmess and

Lind (2011) and Sickert et al., (2014) who reported CIAT resulted in positive change across a range of language tasks.

Despite the statistically significant improvement in all areas of communication impairment across time there was no group effect on any of the outcome measures. This finding is in line with Sickert et al., (2014) who found CIAT and conventional therapy were efficacious with no significant difference in therapy outcomes between the two groups. The results of the current study indicate that within the very early phase of recovery CIAT, which is provided within a group, was as effective as individual impairment based aphasia therapy.

Timing of therapy

All participants commenced therapy within 11 days post stroke and the majority 18 (90%) of participants completed the treatment with the prescribed intensity. Daily (5 days per week) therapy, completed during the very early phase of recovery was tolerated by people with mild to severe aphasia. This study supports findings from Godecke et al., (2012) and Laska et al., (2011) who provided therapy within the same timeframe and found the majority of participants tolerated aphasia therapy at this intensity. The two individuals in this study who did not complete the prescribed intervention became medically unwell during the intervention period, a result that was unrelated to the intervention.

This study also supports previous work by Godecke et al. (2012) to suggest that very early aphasia therapy may lead to significant early communication recovery. This research and findings from Godecke et al. (2012) provides data which suggests there is some merit in commencing aphasia therapy within the first two weeks post stroke in order to take full advantage of enhancing the brain's natural recovery processes in this "time critical window" of opportunity (Murphy & Corbett, 2009, p. 865).

Type of therapy in the very early recovery phase

This study indicates that CIAT, which provides language therapy in a small group, is a viable and possibly more time-efficient therapy option than individual therapy. In a time-poor real world clinical context, aphasia therapy is commonly limited during the very early phase of recovery. Service delivery options are enhanced through the knowledge that the outcomes of CIAT are comparable to individualised impairment based therapy. Concurrently treating two to four people with aphasia provides a practical and efficient level of service delivery during this phase of recovery.

Additionally, this study adds the use of CIAT within the very early post stroke recovery phase to the existing evidence base. Statistically positive results from CIAT were noted at therapy completion and 12 week follow up when therapy was provided in the modified regimen of 45-60 minutes per day for 20 sessions. This intensity modified version of CIAT may be more feasible in the very early phase of recovery when compared to the 30 hours provided over 10 days as outlined in the original study by Pulvermuller et al. (2001) for people with chronic aphasia. As a therapy option in the very early phase of recovery, 45-60 minutes of group therapy per day may be sufficient to achieve a therapeutic effect.

Future Research

This study reinforces the need for further research to differentiate the impact of therapy type and the intensity with which the treatment is provided. Given the lack of difference in findings between the two treatment groups in this and other studies, it is not clear if the treatment itself is the key ingredient for improvement or if the intensity with which the treatment is provided is key. Pulvermuller and Berthier (2008) also raised the idea of exploring the principles of Intensive Language Action Therapy in other communicative contexts. CIAT utilises a request dialogue however a broader range of pragmatic communicative functions may be utilised such as storytelling. It would be of interest to determine whether communicative functions have differing effects on language recovery or on individuals with different communication profiles (Pulvermuller & Berthier, 2008).

Study Limitations

For some measures, the small sample size may have provided insufficient power to detect group differences that might have been attributed to the intervention provided. However, the “very small” effect size for AQ suggests that it is unlikely that the difference would be significant even in a larger study.

Within this study change was noted on the SAQoL (Hilari et al., 2003) at therapy completion. However as a measure of health related quality of life, it should be noted that the SAQoL is made up of a physical score, communication score, psychosocial score and energy score and so it is possible recovery in other areas post stroke may have had an impact on the results for this study.

Treatment was provided during the very early phase of recovery following stroke, therefore it is likely that spontaneous recovery had an impact on the amount of change shown by participants in both groups. The inclusion of a control group, who received usual ward based aphasia therapy, would have strengthened the trial design. This would have allowed for a comparison to be made between higher intensity early aphasia intervention and standard care intervention which may not always be provided with the same intensity.

From therapy completion until the 12 week follow up assessment participants received usual care services. Details of the occasions of service provided were recorded during this period of time however the way in which the data was recorded was inconsistent across sites and so could not be used within this study. Although details of therapy received are not available, participants did not demonstrate a significant change in assessment results during this timeframe. In comparing therapy completion and the 12 week follow up assessment results the amount of change was not significant. This suggests usual care services, received after therapy completion, did not have a significant impact on the 12 week follow up assessment results.

This study closely monitored the amount and frequency of therapy sessions provided to participants however further rigor is required to monitor treatment fidelity in relation to i) amount of adherence to intervention protocols especially since treatment was administered at multiple sites by as many as eight speech and language pathologists and ii) differentiation measures to determine if the therapies being provided are sufficiently different to enable direct relationship claims regarding therapy. One explanation for the lack of significant group difference is that both interventions focused on verbal production and so although the treatments themselves differed in the manner of delivery, the underlying therapeutic mechanism is similar. The focus on verbal production in both therapeutic approaches may have resulted in a similar treatment without a significant therapeutic differentiation between the two approaches. Future aphasia intervention studies require substantial attention to therapy adherence and differentiation to enable conclusive statements regarding therapy efficacy.

Conclusion

This randomised controlled trial investigated the effect of providing a standard aphasia therapy regimen during the very early phase of recovery from stroke. To our knowledge, it is the first study to investigate the use of CIAT within 14 days post stroke. This study demonstrated that participating in very early group therapy was feasible at the prescribed therapy dosage. At therapy completion, improvement was noted on a standardised language assessment and a measure of quality of life. This change was maintained at follow up. A significant difference was noted on a measure of discourse efficiency at follow up. Although improvement was noted there was no difference between the effect of CIAT and individual, impairment based therapy. These findings are encouraging and support the need for further research to establish the effectiveness of treatment within this recovery phase.

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APPENDIX A

CONSTRAINT INDUCED APHASIA THERAPY GROUP THERAPY TREATMENT PROTOCOL

The sessions are one (1) hour playing time.
Several **rounds** may be played within the hour.

There are 4 different sets of 16 pairs of cards of colour photo images. Each set of 16 cards includes high and low frequency words (nouns and verbs), plus objects and actions that are perceptually and/or phonologically similar. Examples are included in the table below. Items were selected from Vanderwort and Snodgrass (1980) and Kim and Thompson (2004). A new set of cards is presented each week (Monday). The picture stimuli within each set of cards can accommodate low and high level language users. The cards do not need to be manipulated according to player makeup within the group at any time.

Target	Item (Example)
Single object	Silver fork
Same object- different colour	Blue fork
More than one of the object	Several forks
Perceptually similar object	Silver spoon
Perceptually similar object- different colour	Wooden spoon
Phonological minimal pair	Moon
Action	Woman singing
Same action - different person	Man singing
More than one of the action	Choir singing

All 16 pairs of cards distributed between the 2-4 players (the therapist does not play).
If only 2 players, deal as to 3 players, with the 3rd set of cards to be a 'pick up' pile.

A 3-sided barrier is provided for each player. This shields each player's view to the front and sides and allows the player to place the cards on the table and view them hands-free.
Players are still able to see the other players over the top of the barrier.

New players can join the group at any session.
Each time a new player joins the group, an open hand demonstration round is played (with different cards, 3 per player) and the rules explained.

Explanations focus on the speech required for the game and are kept to the minimum necessary. Players may need to be prompted during the **activity** to speak rather than use gesture or drawing, to be as specific as they can be and to think before speaking rather than relying on repeating another player's utterance.

Pre-game verbal reinforcement

Give one reminder specific to each player appropriate to their level. Players' language levels are known from initial assessment and daily records from the group.

eg. 'Choose one person when you ask for a card.'

'Try for 2 or 3 words each time.'

If a new player or level not known, remind players to "Say as much as you can, be as specific as you can."

During the game

It is not necessary to give continuous 'on-line' feedback regarding verbal output during the activity. Social reinforcement is provided from the group and so reinforcement will be a natural part of the group dynamic.

End of game verbal reinforcement

Provide one point of feedback to each player, the feedback should provide reinforcement of a particular skill used.

eg. 'Gladys, you were very specific when describing the pictures.'

'Peter, you gave us two words every time'

SHAPING, CUEING AND MODELING

Facilitation is provided by the therapist to support the players' verbal output.

Refrain from cueing / modelling the target word until the player attempts utterance and revision. If the player says the correct thing but is not heard, the player repeats the utterance; if unable to repeat, the therapist can provide the repetition to the group. Provide an opportunity for another player to request clarification/repeat etc. However the therapist may prompt a clarification request.

For word retrieval difficulty, or when the therapist does not know the target, the cue is to prompt a player for more information.

For word production difficulty, the therapist uses cues to elicit a response, gradually reducing cues as the player's skill level improves.

If a player has very limited verbal output, eg. an undifferentiated vocalization/'default sound', the therapist may facilitate and accept a purposeful or different sound. If the player has a limited sound inventory, the therapist may facilitate and accept the initial phoneme of target word.

If a player's utterance is not the complete target word, the therapist should model the word (audibly but unobtrusively) as the activity moves on – providing an accurate model for the players. Correct models may be provided by other players, in which case the therapist need not intervene.

CONSIDERATIONS

Success is getting the message across and target words do not need to be the same on each occasion.

If the player can't say much, the consequence of a player's incomplete or inaccurate utterance is the response of other players. eg. request for clarification or handing over the wrong card.

If the player doesn't hand over the card and says he/she doesn't have the card (but does), do nothing, it will work out.

If players are high level and the activity moves too quickly, increase the level of difficulty according to each player's ability. The player could be prompted for example, to include extra descriptive information, use different words / describe the target in another way, ensure no phonemic errors rather than increasing length of utterance.

If players are of differing receptive/expressive levels, a more verbal player may need to recast their initial word choice and length of utterance, when asked for clarification, to allow another player to understand.

Give more assistance if frustration or irritation levels among the players threaten to outweigh the success or interest in the game.

Recording

A Daily Score Sheet with examples of each player's output and facilitators required provides a record of improvement and guideline for cueing progression.

Table 1. Baseline demographic and stroke characteristics and comparisons for the CIAT and individual therapy participants

	Individual Therapy Group (n = 8)	CIAT Group (n = 12)	p value
Age Mean (SD)	72.6 (14.1)	69.4 (15.0)	0.48 ^b
Female (%)	5 (63.0)	3 (25.0)	0.11 ^c
Stroke type			
Ischaemic (%)	7 (88.0)	11 (92.0)	0.65 ^c
Haemorrhagic (%)	1 (12.0)	1 (8.0)	
Stroke classification			
PACS(%)	5 (62.5)	8 (67.0)	0.61 ^c
TACS (%)	3 (37.5)	4 (33.0)	
Stroke hemisphere:			
Number (%)			
Left	7 (87.5)	11 (92.0)	0.65 ^c
Right	1 (12.5)	1 (8.0)	
Admission mRS ^a score: Number (%)			
2	0	1 (9.33)	0.077 ^c
3	3 (37.5)	0	
4	2 (25.0)	7 (58.33)	
5	3 (37.5)	4 (33.33)	
Admission to assessment			
Mean days (SD)	5.6 (2.3)	4.8 (2.3)	0.75 ^b
AQ score Mean (SD)	45.1 (28.5)	42.5 (27.2)	0.21 ^b
Aphasia Severity (AQ score):			
Number (%)			
Mild (AQ 62.6- 93.6)	2 (25)	5 (41.7)	0.63 ^c
Moderate (AQ 31.3- 62.5)	3 (37.5)	2 (16.6)	
Severe (AQ 0- 31.2)	3 (37.5)	5 (41.7)	
Aphasia Classification			
Number (%)			
Anomic	1 (12.5)	2 (16.66)	0.78 ^c
Brocas	1 (12.5)	3 (25)	
Transcortical motor	1 (12.5)	0	
Wernickes	2 (25)	2 (16.66)	
Conduction	0	2 (16.66)	
Global	3 (37.5)	3 (25)	

Notes: PACS= partial anterior circulation stroke. TACS= total anterior circulation stroke. mRS category comparison: Categories 2- 3 indicate mild- moderate disability and Categories 4- 5 indicate severe disability.

^a mRS is the modified Rankin Scale (Rankin, 1957); ^b Two tailed t- test comparing the individual therapy and the CIAT cohorts; ^c Chi-square test for independence with Fisher's Exact test.

Table 2. Descriptive data for intervention compliance, total therapy time (minutes/ hours) and number of therapy sessions in the intervention phase.

Variables	Individual Therapy Group	CIAT Group	Total
Intervention compliant (%) ^a	8 (100)	10 (83)	18 (90)
Direct language therapy mins (hours) ^a			
Mean	1151.9 (19.2)	1015.8 (16.9)	1070.3 (17.8)
Range	1035- 1200 (17.3- 20)	40- 1200 (0.6- 20)	40- 1200 (0.6-20)
Direct language therapy mins (hours) ^b			
Mean	1145 (19.1)	1130 (18.8)	1136.6 (18.9)
Range	1035- 1200 (17.3- 20)	905- 1200 (15.1- 20)	905- 1200 (15.1- 20)
Number of language therapy sessions ^a			
Mean	19.9	18.3	18.7
Range	19- 20	1- 20	1- 20
Number of language therapy sessions ^b			
Mean	19.9	20	19.9
Range	19- 20		19- 20

Notes: ^a The mean therapy time and the number of therapy sessions reported here includes all participants who commenced intervention in the CIAT group (n= 12) or individual therapy group (n= 8); ^b The mean therapy time and the number of therapy sessions reported here includes only the participants who completed the minimum number of therapy sessions and who participated in the therapy completion and 12 week follow up assessments in the CIAT group (n= 9) and individual therapy group (n= 7).

Table 3. Group outcome measure comparisons

		Baseline Mean (SD)	Therapy Completion Mean (SD)	Follow-up 12 weeks Mean (SD)	Follow-up 26 weeks Mean (SD)
AQ	Individual therapy	45.1 (28.5) (5.6- 81.9) (n=8)	67.6 (33.8) (14.3- 95.5) (n=8)	79.7 (27.5) (21.2- 97.4) (n=7)	88.0 (12.5) (68.0- 96.2) (n=4)
	CIAT	42.5 (27.2) (7.0- 79.6) (n=12)	67.5 (28.6) (8.3- 97.2) (n=9)	67.3 (33.7) (12.6- 97.4) (n=9)	90.0 (12.2) (71.8- 98.4) (n=4)
DA	Individual therapy	5.0 (6.3) (0- 18.8) (n=8)	7.5 (5.4) (0- 13.1) (n=8)	10.8 (6.0) (0-16.9) (n=7)	18.7 (10.8) (9.8- 33.2) (n=4)
	CIAT	1.8 (3.5) (0- 10.0) (n=12)	10.5 (11.0) (0- 26.8) (n=9)	13.3 (11.8) (0- 35.0) (n=9)	16.2 (10.3) (8.4- 33.8) (n=5)
SAQoL	Individual therapy	2.2 (1.6) (0-4.2) (n=7)	3.9 (0.7) (2.7- 4.8) (n=8)	3.9 (0.7) (3.0- 4.7) (n=7)	3.9 (1.0) (2.7- 4.8) (n=5)
	CIAT	2.2 (1.5) (0- 3.9) (n=8)	3.6 (0.6) (2.6- 4.3) (n=8)	3.9 (0.6) (3.2- 4.5) (n=8)	3.5 (0.7) (2.9- 4.5) (n=4)

Notes. At the baseline assessment four participants, in the CIAT group and one participant, in the individual therapy group, were unable to complete the SAQoL. At therapy completion, 12 and 26 week follow up assessments one participant, in the CIAT group, refused to complete the SAQoL. At the 26 week follow-up assessment one participant, in the CIAT group, refused to complete the WAB and the SAQoL. At the 26 week follow-up one participant, in the individual therapy group, refused to complete the WAB and the discourse task.

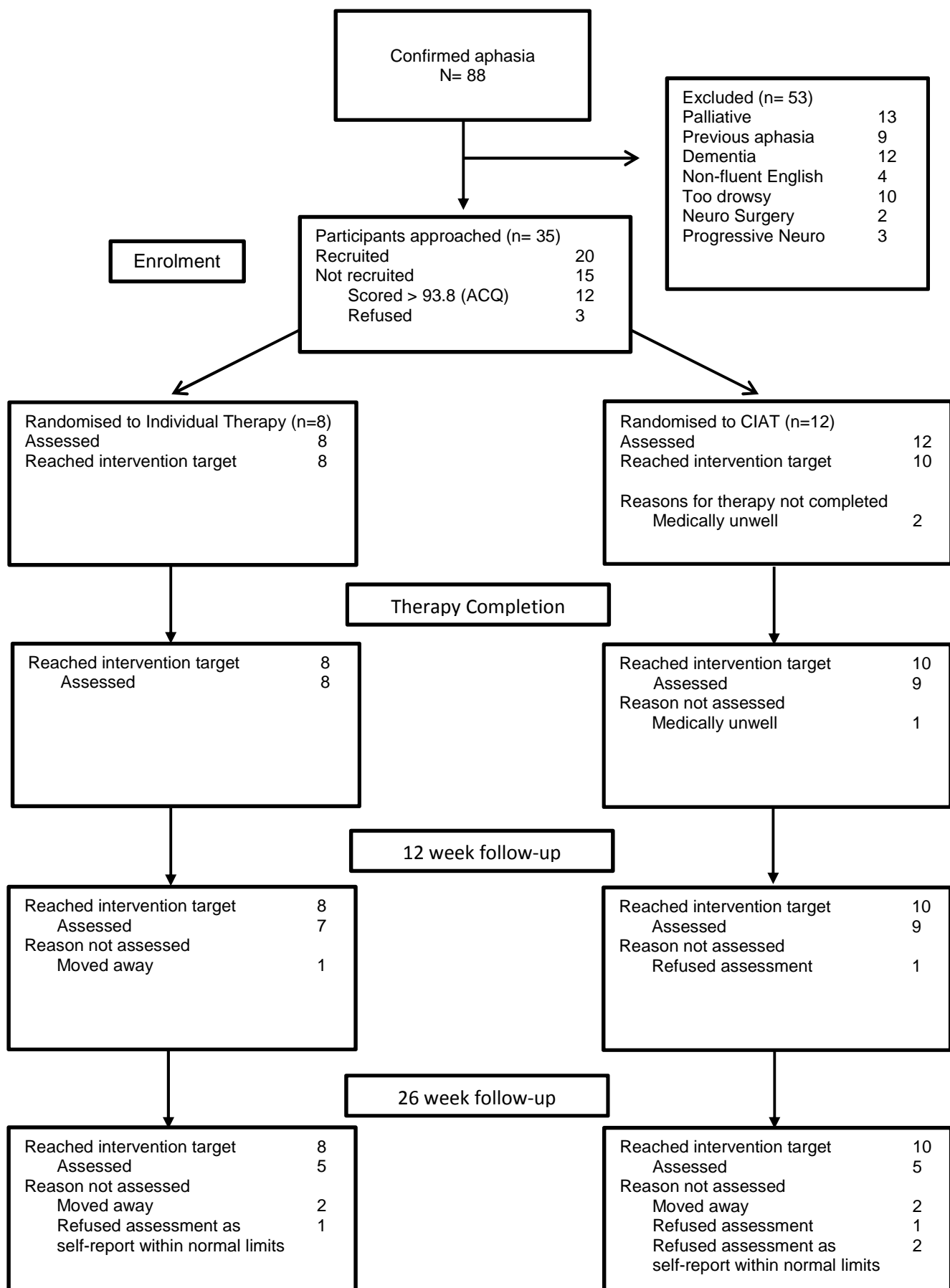


Figure 1. Progress of participants through the study

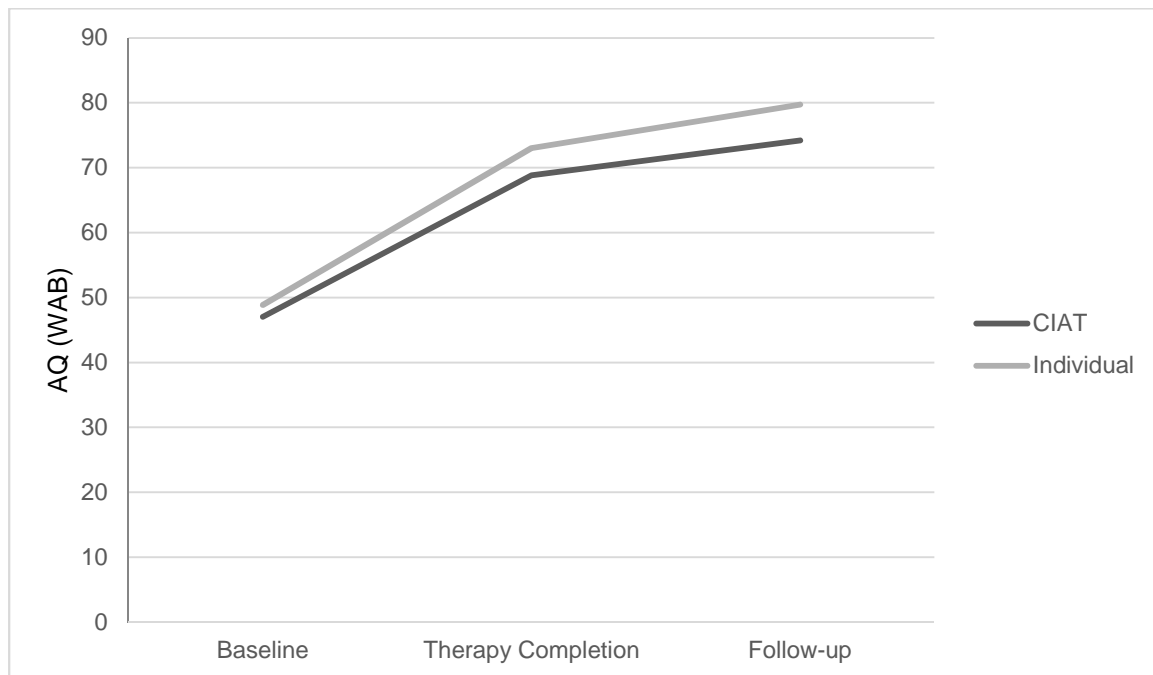


Figure 2. AQ comparisons at baseline, therapy completion and 12 week follow-up

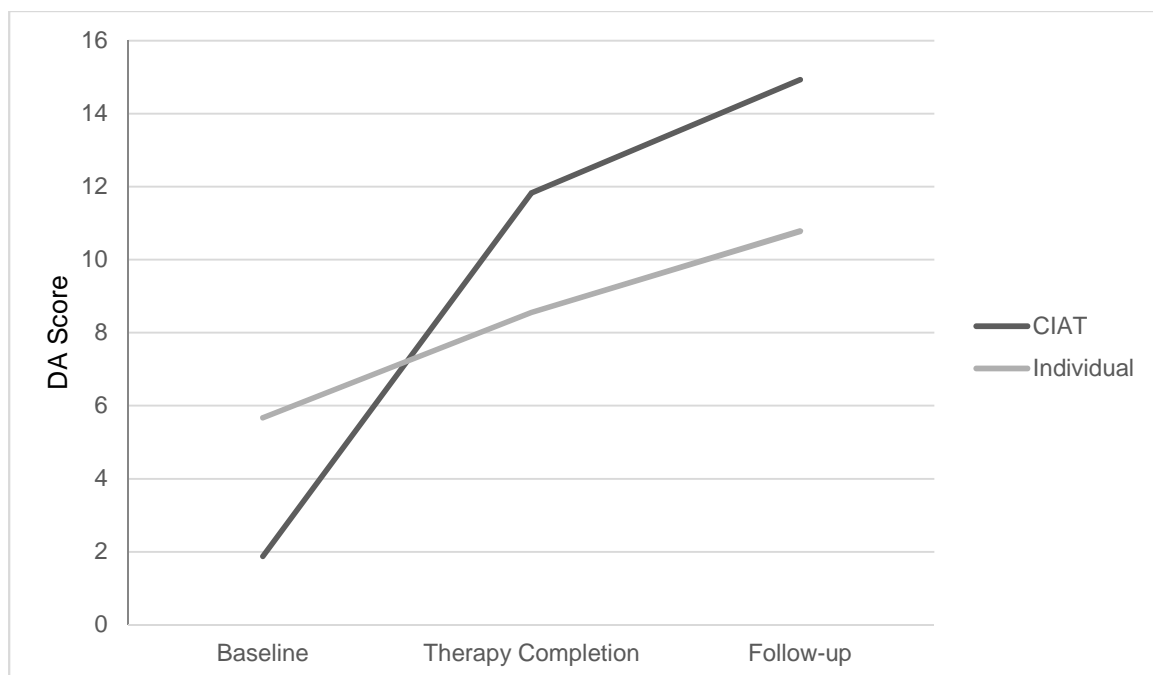


Figure 3. DA comparisons at baseline, therapy completion and 12 week follow-up

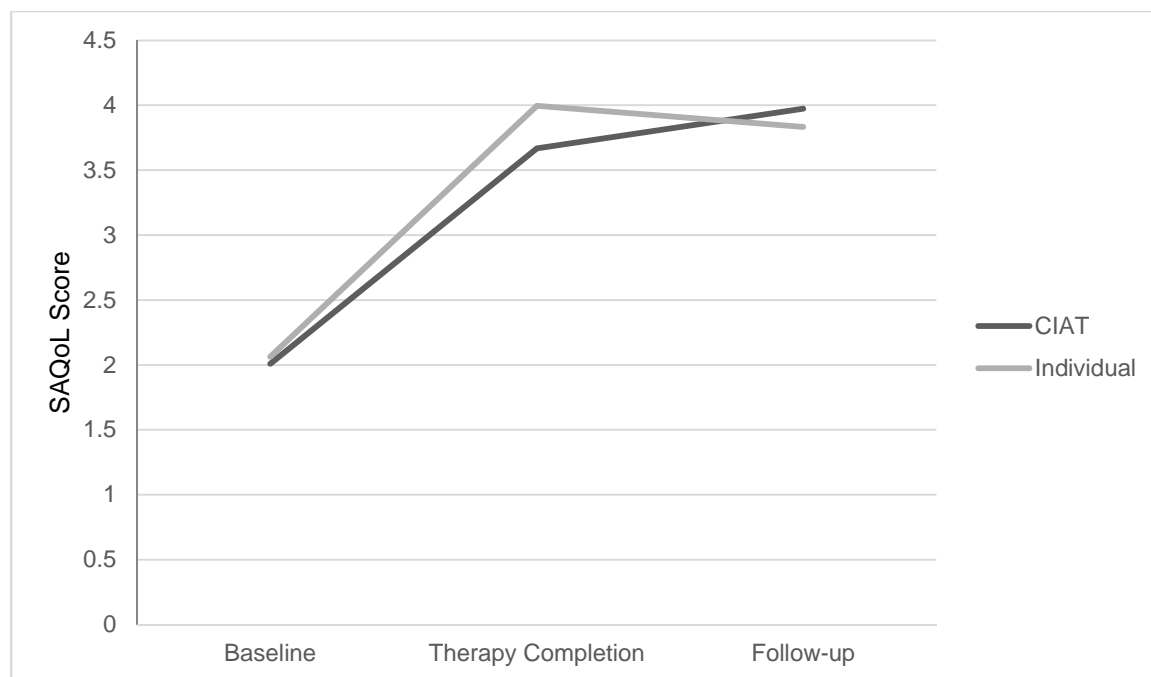


Figure 4. SAQoL comparisons at baseline, therapy completion and 12 week follow-up