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RESEARCH

Effectiveness of enhanced communication therapy in the first four months after stroke for aphasia and dysarthria: a randomised controlled trial

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Abstract

Objective To assess the effectiveness of enhanced communication therapy in the first four months after stroke compared with an attention control (unstructured social contact).

Design Externally randomised, pragmatic, parallel, superiority trial with blinded outcome assessment.

Setting Twelve UK hospital and community stroke services.

Participants 170 adults (mean age 70 years) randomised within two weeks of admission to hospital with stroke (December 2006 to January 2010) whom speech and language therapists deemed eligible, and 135 carers.

Interventions Enhanced, agreed best practice, communication therapy specific to aphasia or dysarthria, offered by speech and language therapists according to participants' needs for up to four months, with continuity from hospital to community. Comparison was with similarly resourced social contact (without communication therapy) from employed visitors.

Outcome measures Primary outcome was blinded, functional communicative ability at six months on the Therapy Outcome Measure (TOM) activity subscale. Secondary outcomes (unblinded, six months): participants' perceptions on the Communication Outcomes After Stroke scale (COAST); carers' perceptions of participants from part of the Carer COAST; carers' wellbeing on Carers of Older People in Europe Index and quality of life items from Carer COAST; and serious adverse events.

Results Therapist and visitor contact both had good uptake from service users. An average 22 contacts (intervention or control) over 13 weeks were accepted by users. Impairment focused therapy was the approach most often used by the speech and language therapists. Visitors most often provided general conversation. In total, 81/85 of the intervention group and 72/85 of the control group completed the primary outcome measure. Both groups improved on the TOM activity subscale. The estimated six months group difference was not statistically significant, with 0.25 (95% CI –0.19 to 0.69) points in favour of therapy. Sensitivity analyses that adjusted for chance baseline imbalance further reduced this difference. Per protocol analyses rejected a possible dilution of treatment effect from controls declining their allocation and receiving usual care. There was no added benefit of therapy on secondary outcome measures, subgroup analyses (such as aphasia), or serious adverse events, although the latter were less common after intervention (odds ratio 0.42 (95% CI 0.16 to 1.1)).

Conclusions Communication therapy had no added benefit beyond that from everyday communication in the first four months after stroke. Future research should evaluate reorganised services that support functional communication practice early in the stroke pathway.

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Introduction

The UK National Audit Office recently estimated that the direct care cost for people with stroke was "at least £3 billion annually," with around a third of stroke survivors experiencing lifelong disabilities.[1] Randomised controlled trials and systematic reviews have shown the effectiveness of specialist stroke units.[2] As stroke units are almost universally provided,[3 4] there is a need to explore the components of the "black box" of care.[5] Speech and language therapy is one such component, and it includes a variety of approaches in clinical practice.[6 7] The prevalence of persisting difficulties with speech (dysarthria) and language (aphasia) is 30 to 50 per 100 000 population six months after stroke.[8] These communication difficulties restrict independence and social participation, and negatively affect informal care givers.[9-11]

In the draft clinical guideline on stroke rehabilitation from the National Institute for Health and Clinical Excellence (NICE) (revision due 2012), speech and language therapy for people with aphasia was a key priority, although the timing, intensity, and type of therapy were not specified.[12] Given that stroke can result in lifelong disability, commissioners need to know at what point in the stroke pathway speech and language therapy for aphasia is recommended. Despite a firm consensus that speech and language therapy is beneficial,[6 7 13] clinical effectiveness remains unknown, and no reports from randomised trials have mentioned cost effectiveness.[14] Cochrane reviews and recent guidelines highlight the absence of a single randomised controlled trial of treatments for dysarthria,[6 15] and the 30 trials in the aphasia review leave considerable uncertainty.[16] The review's tentative conclusion reports "some indication" of effectiveness with speech and language therapy.[16] A recently published update that includes the current study examines whether speech and language therapy is better than no therapy at improving functional communication (see our discussion).[17] It then examines whether this remains when therapy is compared with "social support or stimulation" (such as art, dance, and informal unstructured communicative interactions).

The ACT NoW study (Assessing Communication Therapy in the North West)[18] was commissioned and funded by the UK's NIHR Health Technology Assessment Programme. It used a mixed methods approach (randomised controlled trial and qualitative study) to examine the effectiveness, cost effectiveness, and service users' views and uptake of a well resourced, flexible intervention offered by speech and language therapists in the first four months after stroke compared with an equivalent amount of contact but not therapy provided by "visitors" (employees not volunteers). The comparison examines whether speech and language therapy provides added benefit beyond that likely from regular attention. This paper covers only the results of the randomised controlled trial. Detailed reports of the methods, intervention, control arm, health economic evaluation, and qualitative study have been published.[18 19]

Methods

Setting

This multicentre study recruited from 12 English sites from December 2006 to January 2010. Sites were NHS hospitals that admitted adults with acute stroke . All had a speech and language therapy service with expertise in aphasia and dysarthria, and they agreed to reorganise their service to provide continuity of care from inpatient to community setting and to work to a consensus based intervention.

Participants

Adults admitted to hospital with a stroke were eligible for inclusion if they had impaired communication due to aphasia or dysarthria, were considered by a speech and language therapist as likely to benefit from this intervention, and gave informed consent (or proxy consent by carers). The intention was to be as inclusive as possible since the intervention was a flexible, enhanced version of current best practice and intensity could be modified to individual need.

Exclusion criteria were based on practical resource limitations such as the participant living outside the area served or being unable to communicate in the English language (therapists believed that translation or interpretation services were inappropriate for aphasia). Therapists also excluded people for whom intervention was deemed unsuitable—for example, those receiving end of life care or with pre-existing learning disabilities or dementia likely to prevent benefits from therapy, subarachnoid haemorrhage, or serious medical conditions (such as terminal disease); patients unable to complete the eligibility screening after three attempts; and patients whose communication problems resolved or were likely to resolve without intervention.

Procedure

Initially, all stroke admissions to hospital were screened by speech and language therapists to determine eligibility. However, this proved unnecessary, and (from April 2008) speech and language therapists screened only those with suspected communication problems to confirm the presence and persistence of communication problems, provide a differential diagnosis (aphasia, dysarthria, or both), determine the severity of the communication problem, and rule out non-obvious exclusion criteria. They used the Frenchay Aphasia Screening Test (FAST),[20] or informal assessment if the communication problems were too severe, and the impairment and activity scales of the Therapy Outcome Measure (TOM).[21] Dysarthria was diagnosed and its severity determined by a TOM rating based on the speech sample from the FAST picture description task and conversation. The presence or absence of dysphagia (swallowing) was also diagnosed. Apraxia of speech was outside the remit of this study.

Before randomisation, research assistants also rated patients on the 10 item Modified Barthel Index[22] with the help of the multidisciplinary team. The Barthel Index gives a score out of 20 and indicates severity of overall disability (beyond communication). Since the communication impairment was specifically assessed (TOM), no other stroke severity measures were required.

Consent

Before randomisation of eligible patients, the speech and language therapists provided them with an "aphasia friendly" leaflet about their diagnosis and asked if they would like to meet a research assistant to discuss the study. The multidisciplinary team was also alerted to the diagnosis. Speech and language therapists did not provide further communication support to participants, their families, or the multidisciplinary team until after randomisation. Research assistants immediately met

potential participants to provide study information. Participants were given 24 hours to allow discussion with their family. We used aphasia friendly, accessible information materials developed in collaboration with our Research User Group partners.[18 23] When necessary, proxy consent was requested, and research assistants later gave regular opportunities for participants to directly provide or withdraw their consent.

Randomisation

To ensure concealment of allocation, randomisation was by an external, independent, web based randomisation service from a trials unit activated by research staff. Randomisation was stratified by the severity of communication impairment and recruiting site. Stratification by diagnosis was also requested (aphasia only, dysarthria only, or both), but during data checks after study completion it became clear this had not occurred. Participants were randomised using a 1:1 allocation ratio and randomly permuted blocks.

Intervention

The speech and language therapy was an agreed, best practice, flexible intervention developed by speech and language therapists for delivery early after stroke in usual care settings but better resourced than standard practice at most sites.[18] In this study "early" refers to the acute to post-acute period of the stroke pathway (the first four months) and is used to distinguish this clinical population from those with chronic aphasia or dysathria. This allowed therapy to start as soon as clinically indicated and, if deemed appropriate, up to three contacts per week for up to 16 weeks, following participants along their stroke pathway. Start date, duration, and frequency of therapy varied within and between participants, as determined by each therapist's clinical judgment and agreement with the participant about what was appropriate. This was not a "one size fits all" intervention, and these levels of therapy were not prescriptions but were fixed upper limits. Although well resourced, this study was not intended as a trial of different levels of intensity.

A manual was developed by the therapists setting out specific components of the intervention and service delivery, and can be described as a set of best practice guidelines and a compendium of resources. There were six core components of the intervention (see box). Adherence was ensured by an agreed coding system for all contacts and by employing a part time therapy monitor, an experienced speech and language therapist. Therapists attended regular facilitated peer group meetings where sites presented data on eligibility decisions and descriptive single case therapy. The therapy monitor visited sites to observe delivery and inspect the coded data.

Control

A similar frequency and amount of social contact was offered to those in the control group by employed visitors (not therapists or volunteers). Visitors had excellent social skills and general competency and were trained to deliver social attention absent of any intuitive form of communication therapy or strategy. They followed a short manual allowing everyday activities (such as conversation, television, music), but visits were mostly led by participants. Visitors were monitored to ensure adherence, including visits from the part time visitor monitor, who selected and trained visitors, observed their contact with participants, inspected the coded data from each contact, facilitated group supervisory meetings of visitors, and provided one to one support for visitors.

Objectives and outcomes

The randomised controlled trial aimed to evaluate the clinical effectiveness of the communication intervention compared with the control social contact six months after entry to the study from the perspective of different stakeholders:

- Therapists' ratings of participants' functional communication (primary outcome)
- Participants' self reported functional communication and quality of life
- Carers' perceptions of participants' functional communication
- Carers' own wellbeing
- Carers' quality of life
- Adverse events.

For the primary outcome, a semi-structured conversation between each participant and an unfamiliar communication partner (study research assistant) trained in communication supportive techniques was videotaped. An independent speech and language therapist, blinded to treatment allocation and not involved in treating the study participants, rated functional communication on the communication activity scale of the Therapy Outcome Measure (TOM). Despite its ecological validity, conversation between a participant and a familiar partner was not used as an outcome because of the difficulties in standardising the content, amount, and support provided. The chosen method (unfamiliar partner plus blinded rating of videotapes) has demonstrated validity and reliability.[24]

Secondary outcomes were:

Participants' perception of their functional communication and quality of life—Based on the validated 20 item Communication Outcomes After Stroke (COAST) scale,[25] which covers both understanding and expression in a range of communication situations, including five items on quality of life. The score is converted to a percentage, and higher scores indicate better outcomes.

Carers' perceptions of participants' functional communication—Based on the relevant 15 questions on the validated Carer COAST scale.[26] Higher scores indicate better outcomes.

Carers' wellbeing—Based on the 15 item Carers of Older People in Europe (COPE) Index.[27] There are three subscales: negative impact (a high score is a poor outcome as it indicates stress), positive impact, and quality of support (high scores are good outcomes as they indicate satisfaction and support).

Carers' quality of life as affected by participants' communication problems—Assessed with the relevant five questions from Carer COAST.[26] Higher scores indicate better outcomes.

Adverse events—Death, subsequent stroke, events leading to increased hospital stay or readmission to hospital.

A qualitative study was prospectively nested within the randomised controlled trial to support the interpretation of the trial findings in a way that would help commissioning decisions. Qualitative interviews with participants from both arms of the trial provided rich detail on service users' perceptions and their views on the impact of early regular contact and are reported elsewhere.[18 19]

Core components of the intervention

1. *Assessment*—Initial and ongoing, standardised, functional, case history, goal setting
2. *Information provision*—Communication problem, strategies or equipment to assist communication, intervention plan, therapist opinion of progress, available information resources and support networks
3. *Provision of communication materials*—Communication book for recording activities, an "alternative and augmentative communication device" if required
4. *Carer contact*—Discussion and provision of information, observation and participation in therapy, conversation training for patient's partner, preparation for the end of the research intervention
5. *Indirect contact*—Written descriptions of needs, abilities, and strengths; discussions with clinical teams; goal planning with multidisciplinary team
6. *Direct contact*—Therapy to improve language skills at all levels of the World Health Organisation ICF model: Impairment (improving language skills), Activity (compensatory strategies), Participation (developing confidence, accessible information)

Blinding

In most rehabilitation trials it is impractical and unacceptable to blind participants and those delivering the intervention to the allocation group. We endeavoured to blind the research assistants who collected the outcome data (password protected data related to allocation, participants asked not to mention allocation when visited). The risk of bias for the primary outcome was minimised by using expert speech and language therapists who did not know the participants and were blinded to allocation to rate the videotaped structured conversation, although the therapists may have seen communication aids in use. We felt strongly that participants' and carers' reported outcome measures should be included as secondary outcomes although they could not be blinded.

Statistical analysis

The primary analysis used regression methods to estimate group differences in outcomes at six months after adjustment for the intended stratification criteria (site, diagnostic group, and baseline severity of communication impairment on the Therapy Outcome Measure). The adverse event rates were compared without adjustment as they were not anticipated to be sufficiently common to allow multifactorial analysis.

Analyses included all participants assigned to their allocation group regardless of adherence to protocol—a complete case analysis under the "intention to treat" approach. Participants who were lost to follow-up or declined assessment were excluded. Those known to have died were included as having the worst possible outcome (no functional communication on the primary outcome). No other imputation was undertaken.

For outcomes assessed with COAST and Carer COAST, we compared valid assessments (that is, those with at least 90% of applicable items answered). No adjustment took place where responses between participant and carer might be construed as incompatible, as the instruments were designed to respect the individual's self perception.

Sensitivity analysis was used to re-analyse the primary outcome data in several ways to assess how robust conclusions were to the choice of approach. Non-adjustment for intended stratification criteria, allowance for possible therapist effects, omission of people who had died, and per protocol analyses were all considered. The exact choice of such sensitivity analyses was inevitably data driven to some extent. For example, if primary analysis suggested a group difference the robustness of this conclusion needed to be examined (for example, allowance for possible therapist effect). Conversely, if primary analysis did not suggest a group difference the sensitivity analysis would focus on approaches that might identify possible explanations (such as per protocol analysis). We conducted pre-planned subgroup analysis of type of communication problem (aphasia or dysarthria) and of severity.

All statistical analyses were undertaken in STATA (version 10.1).

Sample size determination

The original protocol proposed a total sample size of 300 participants for 90% power to detect a difference of 0.5 points on the primary outcome of the Therapy Outcome Measure. The target effect size of 0.5 on the Therapy Outcome Measure was chosen as it is the smallest measurable difference on the scale. This calculation allowed for differential clustering between the two arms due to different numbers of therapists and visitors, with intra-cluster correlation coefficient of 0.05 in each arm.

Recruitment was slower than anticipated, leading to revision of the target. The observed standard deviation of the primary outcome for the first 43 recruited participants, adjusted as for primary analysis, was 1.1 points. The initial plan to incorporate therapist effects in the primary analysis was dropped as there was insufficient power to examine these potential effects and the independent Steering Committee considered an intra-cluster correlation coefficient of 0 to be a more reasonable assumption given our confidence in our monitoring system that ensured therapists adhered to the therapy manual. This led to recalculation of a target sample size of 170 participants to give 80% power at the 5% significance level to detect a difference of 0.5 points, allowing for approximately 10% loss to follow-up.

Interim analyses and stopping guidelines

No formal stopping rule was applied to interim analyses reported to the Data Monitoring and Ethics Committee. The videotapes for assessment of the primary outcome data were stored for distribution in batches. This precluded early stopping as the primary outcome remained largely unmeasured at the time of the committee meetings. Consequently no adjustments were made to the significance levels or confidence intervals in presented analyses.

Participant withdrawal criteria

No specific withdrawal criteria were defined for the study. Participants were able to withdraw their consent and stop their allocated intervention prematurely. In these cases they could choose to enter standard services for speech and language therapy at their site. Regardless of this potential protocol deviation, research assistants attempted to collect outcome data for all participants.

Given that participants were assessed for eligibility soon after stroke admission, specific exclusion criteria might come to light after randomisation. In these cases, the independent Data Monitoring and Ethics Committee was consulted as to the appropriateness of the participant continuing in the trial.

Results

Of the 389 patients who were eligible and received study information, 170 (44%) consented to enter the randomised controlled trial (fig 1⇓). Eighty five people were randomised to each group (with 72 from the control group and 81 from the intervention group included in primary analysis). The low eligibility rate (21% of all admissions or those with a suspected hyperacute communication problem) was scrutinised throughout to ensure it was a valid reflection of speech and language therapists' usual decision making. The main reason therapists excluded people after screening was due to false positives: in 43% of cases (690/1632) communication problems had resolved or were too mild to require intervention. In contrast, fewer than 4% (59/1632) were excluded because their communication problem was too severe. Participants' general health problems, including stroke severity and severe cognitive impairments, accounted for another 43% of exclusions (694/1632).

The sample had good external validity, as those who consented were similar in their measured characteristics to those who declined (table 1⇓). The latter seemed to have slightly less severe communication impairment and, conversely, slightly more restrictions at the activity level of measurement, although there were missing data from those who declined. There was a good age range within this predictably older clinical population, most of whom had aphasia (alone or with dysarthria), and around half had impaired swallowing. Screening and recruitment procedures moved swiftly. The median time from stroke admission to randomisation was 12 days. Of course, the speech and language therapists had first contact with potential participants earlier (pre-randomisation determination of diagnosis and severity, etc) at a median of five days after admission.

Randomisation achieved balance between groups on the stratification factors and several other demographic measures (table 2⇓). Ethnicity was undisclosed in two cases but otherwise did not differ between groups, with 98% of the overall sample described as white. Socioeconomic status was not collected. On average the control group was slightly more severely affected than the intervention group in terms of activity level communication, dysphagia, and activities of daily living. Most participants (79%) had an identified carer who was willing to complete outcome measures. Most carers who took part were female family members in the same household, not in paid employment, and were younger than the stroke participants (mean age 56 years (range 21–80)).

Treatment fidelity and participant follow-up

One participant from each group was withdrawn after randomisation on the advice of Data Monitoring and Ethics Committee. Information came to light that questioned the validity of one participant's consent, and proxy consent was declined. The other lived out of area and could not be treated once discharged.

Protocol violation was more common in the control group. Of the 72 participants who completed primary outcome assessment, 18 (25%) received some speech and language therapy (average of 3 hours) before assessment. In the intervention group two out of 81 participants (2%) received some non-study speech and language therapy. Analysis of factors associated with study completion without protocol violation (that is, predictive of inclusion within the per protocol analysis) suggested that younger participants with more disabled communication were more likely to breach protocol. Sensitivity analyses therefore accounted for these factors as well as the baseline difference in stroke severity (fig 2⇓) when comparing the per protocol groups.

Eight participants died, and 12 declined follow-up in the control group, while four died and three declined follow-up in the intervention group. The median (interquartile range) time to outcome assessment for the remaining participants was around the intended six month point (180 (169–182) days).

Intervention and control contacts

Data on the timing, amount, and content of the intervention or control contacts delivered to each arm are briefly summarised below as they are described in detail elsewhere.[18]

Intervention—Speech and language therapy was delivered as intended, flexibly tailored to individual need and started on average two weeks after stroke. It involved an average of 22 contacts (18 hours) over 13 weeks, in both hospital and community settings. Because of practical considerations, therapy was always delivered on a one to one basis. Seventy three (87%) participants received therapy led by a senior therapist, and 42% of all contacts were made by senior therapists. The actual delivery of the six core components (see text box) is summarised in table 3⇓, which shows that every therapy participant received further assessment and direct contact. Table 4⇓ breaks down the "direct contact" component and shows that 93% of participants received impairment focused therapy. In addition to this "head count" analysis, which essentially shows whether a person received a component, it is useful to explore which components were used most often. This showed that 53% of activities were direct contact, 15% were carer contact, 14% were assessment, 11% indirect contact, 8% information provision, and 3% the provision of communication materials (difficulty coding information provision means the total slightly exceeds100%). When the most common therapy component, direct contact, is broken down into specific therapy approaches, impairment focused therapy accounted for half of the direct contact activity (and almost a quarter of activity overall).

Control—The control social contact was successfully delivered. Our feasibility study found that using volunteers to deliver the attention control was impractical and, counterintuitively, very expensive.[18] Therefore, part time visitors were employed (not volunteers) throughout the main randomised controlled trial. There were seven women and two men, aged 26–61 (mean 48) years. Some had taken early retirement, others cared for young children. Their work experience was at varying levels of seniority from a receptionist to a retired head teacher. Five had degree level education. All had well developed social skills and were natural communicators capable of expressing warmth and empathy appropriately. On average, 19 contacts were provided per participant (15 hours), starting about the same time (day 17) as the therapists' first contacts with the intervention group. Continual training and support for visitors by the visitor monitor ensured protocol adherence and human resource management. Adding in the additional NHS speech and language therapy received by the 18 participants who refused their allocation meant that controls overall received an average total of 23 contacts (visitor plus usual care), almost identical to the average of 22 contacts received by those in the intervention arm. Most visitors prepared a rough plan for each visit based on what they picked up about a participant's interests, family, and job, but generally let the sessions be patient led. The activity that occurred most frequently was, not surprisingly, conversation. Other activities occurred, but far less often (such as reading to the participant; games; television, radio, music; and "other,"

which included jigsaws, looking at photographs, going out, making coffee).

Primary outcome

There was an overall improvement of 0.8 on the activity level scale of the Therapy Outcome Measure from pre-randomisation baseline scores taken by a speech and language therapist. This suggests a clinically meaningful gain in functional communication, from a baseline mean of 2.4 ("limited communication, relies on cues and context to make basic needs understood") to a mean of 3.2 six months later ("consistently able to make needs known, communicates beyond here and now"). However a similar magnitude of improvement was seen for both arms, with the control group starting and completing the study with slightly lower scores.

Primary outcome analysis was conducted by comparing the between group difference in Therapy Outcome Measure activity scores at six months. The mean was slightly higher in the intervention group and was a little less variable (table 5⇓). The planned primary analysis, adjusted for intended stratification factors and including deaths, favoured speech and language therapy but was not statistically significant. The confidence interval included the 0.5 point difference the study was powered to detect but also included zero.

Sensitivity analyses

The primary outcome measure was further explored using various sensitivity analyses: exclusion of deaths; extra adjustment for baseline differences in Therapy Outcome Measure activity and Modified Barthel Index; restricting the analysis to per protocol groups with adjustment for baseline age (as age was identified as predictive of outcome), Therapy Outcome Measure activity, and Modified Barthel Index; and restricting the analysis to per protocol groups with adjustment for baseline age, Therapy Outcome Measure activity, and Modified Barthel Index and excluding deaths.

As shown in figure 2⇓, the findings are robust. However the primary analyses are adjusted, there is no suggestion of an added benefit of speech and language therapy intervention over and above the control social contact. In particular, exclusion of deaths and adjustment for baseline differences both move the estimated treatment difference to near zero and remove the continued possibility of the targeted 0.5 point difference between groups. This suggests evidence of absence of a treatment effect rather than simply absence of evidence. The two per protocol analyses give similar conclusions to those from their intention-to-treat counterparts. This removal from analyses of people who refused their allocation and received NHS speech and language therapy at some point (including the 18 control participants allocated to see only a visitor) suggests that the protocol deviation did not cause a dilution of treatment effect. Consideration of possible clustering due to therapist effects, by inclusion of lead therapist or visitor as a random effect, did not alter the analyses as estimated intra-cluster correlation coefficients were zero in both trial arms.

Subgroup analyses

Subgroup analyses were provided for future systematic reviewers, but there was no suggestion that the treatment effect differed between subgroups by diagnosis or by baseline severity of communication impairment. Diagnostic categories are not exclusive because presenting these as "any aphasia" (which may include dysarthria too) is more relevant to future service delivery than "only aphasia." Analyses used the primary analysis method (inclusion of deaths and adjustment for intended stratification factors but not for observed baseline imbalances). The conclusions are similar as for the overall cohort, with wider confidence intervals resulting from reduced sample sizes. For completeness and visual comparison these results are included in figure 2⇓.

Secondary outcomes

Table 5⇓ presents the summary statistics and analyses of the secondary outcomes after adjustment for the intended stratification criteria. All outcome measures present a consistent pattern from the perspectives of different stakeholders—that is, participants and carers. Groups were similar for all scales of the COAST, Carer COAST, and COPE measured at six months, and for all subscales (not shown). This means there was no evidence of added benefit of the speech and language therapy intervention over and above the control social contact on participant or carer perceptions of the participant's communication, nor on carer perceptions of impact on themselves in terms of their own quality of life or wellbeing.

Serious adverse events

There were no suspected adverse reactions and no unexpected serious adverse events during the trial. Overall, 12 participants died, six survived further strokes, and four others required extended or repeat hospitalisation. Numbers of each of these events were higher in the control group, but there were no statistically significant differences between the groups in either overall serious adverse events (odds ratio 0.42 (95% confidence interval 0.16 to 1.1)) or death rates (odds ratio 0.48 (0.14 to 1.6)) but also low power to detect such differences. However, given the similarity in outcome between the groups, it would be challenging to hypothesise a mechanism for increased adverse events in either group.

Discussion

Principal findings

People with aphasia or dysarthria, who were offered well resourced but individually tailored, best practice, speech and language therapy in the first four months after stroke, showed similar levels of functional communication ability at six months as those who received visits from a non-therapist employed to provide an unstructured social contact consisting largely of informal conversation but no specific communication training. Similarly, there was no added benefit for any outcome measure reported by participants or carers, for serious adverse events, or for any sensitivity or subgroup analysis.

Although both groups improved on the primary outcome, this could have been due to spontaneous recovery, regression to the mean, or general support from a therapist or visitor. Data on resource use showed that users accepted an average of 22 contacts over 13 weeks (from therapists or visitors) of the maximum available to them. These provide useful acceptability data to any researchers considering providing more intensive early intervention. The nested qualitative study reported elsewhere helps interpret the randomised controlled trial and resource use findings, suggesting that users value early regular contact (with a therapist or visitor) that provides an opportunity to practise functional communication and has a positive impact on their confidence and mood.[19]

Comparison with other studies

This is the first trial of speech and language therapy for people with dysarthria, as none was identified in the Cochrane review[15] or recent literature searches conducted for the updated clinical guideline due out in 2012.

The recently updated Cochrane review of aphasia identified 39 trials (including this one) evaluating several different interventions and modes of delivery and at different points in the stroke pathway.[17] It does not include an analysis of trials in the early stage of the pathway, so this comparison is made below. Most (19/39) of the included trials compared speech and language therapy with no therapy. Unsurprisingly, given the potential placebo effect, they found significant functional communication benefits from therapy. The review's second comparison examined the important question of whether the benefit remains when therapy was compared with "social support or stimulation." Of the seven included trials, only two provided data on functional communication (ours and David et al 1982[28]), and no evidence of difference was found. The trial by David et al may be more relevant for people with chronic aphasia as their participants were between four and 432 weeks after stroke.[28]

The international evidence base for the acute phase of the stroke pathway is now quite strong, as ACT NoW is the third trial to publish in the past year. Two recent trials in Sweden and Australia evaluated "very early" speech and language therapy for people with aphasia (not dysarthria).[29 30] They recruited earlier than ACT NoW (around 3 days versus our 12), but they provide different pieces of evidence about early intervention, as they used different control comparators.

The Swedish study randomised 123 patients with ischaemic stroke and found no evidence of difference in primary or secondary outcomes between a control group (no contact) and a group allocated to 21 days of 45 minutes per day of language enrichment therapy as measured at 21 days.[29] Functional and impairment level measures were used. This is a useful trial with which to answer queries about whether the ACT NoW intervention was intensive enough or early enough. It found no evidence for the effectiveness of an intensive programme of impairment focused therapy "very early" after a stroke. This is resonant of a UK study which found no evidence of difference on impairment level measures for five versus two hours per week of speech and language therapy for 12 weeks (and lower user acceptability for the higher intensity).[31] The Cochrane review also warns of the higher dropout from high intensity interventions across the stroke pathway.[17]

The Australian trial[30] was designed as a pilot and randomised only 59 people with aphasia to either daily, individually tailored, impairment based, speech and language therapy (around 2.5 hours per week over the first three weeks) or to usual care (not more than once a week), with functional and impairment level outcomes measured at acute hospital discharge or four weeks. The results suggested that, in those who could interact for up to 30 minutes, very early intensive speech and language therapy was feasible and might improve immediate outcomes when compared with almost no speech and language therapy. Methodological issues may temper their positive conclusions. As it was a pilot study, randomisation was not stratified (such as for severity), and the authors warned of the possible impact of baseline imbalance favouring the intervention group, including the measure subsequently used as the primary outcome. Also "picture description," a task practised at every therapy session, was a component of the primary outcome measure, raising the possibility of a task-specific practice effect rather than a true difference in functional outcome. The lack of a control group that received a similar intensity of attention prevented discrimination between effects of speech and language therapy or of general psychosocial benefits from regular contact. The ACT NoW study specifically addressed this.

One other study of relevance to this discussion is the Cochrane review of repeated task practice. Our suggestion that regular contact with a therapist or visitor provided increased opportunity to practise everyday communication fits with the review's positive findings, although they evaluated non-communication tasks.[32]

Strengths and weaknesses of ACT NoW

Concerns about the feasibility of a randomised controlled trial of this complex intervention for a heterogeneous clinical population proved unfounded. A robust evaluation was successfully completed with low risk of bias, valid and reliable outcome measurement, and results generalisable to international stroke services. The involvement of service users as research partners throughout the process from design to dissemination has greatly improved this study. The use of mixed methods, nesting a qualitative study within the randomised controlled trial,[18 19] added richness to the interpretation of the randomised controlled trial results and is recommended good practice.[33]

A smaller than expected proportion of patients admitted to hospital with stroke was deemed eligible, but exclusions were prospectively checked and were justifiable (such as false positives from screening). It would be contradictory to argue that the intervention would have been more effective for those patients who were excluded by practising therapists as being unlikely to benefit. Concerns that different clinical populations (people with aphasia versus dysarthria) were inappropriately subjected to a "one size fits all" intervention can be relieved by referring to the detailed description of the individualised approach taken to assessment and intervention, and the presentation of planned subgroup analyses for aphasia and dysarthria.[18] Although it is theoretically possible that small differences within subgroups were missed, our data do not suggest different effect sizes by impairment subgroup. Although 18 people refused the control allocation and received some usual care speech and language therapy, we know from our additional per protocol analysis that this did not dilute any effect. It was highly predictable that people would prefer contact labelled "therapy" rather than the control. It follows that being in a trial further raises expectations as participants are offered a 50:50 chance of an enhanced package of that current service.

A strength of ACT NoW was the move away from traditional surrogate measures of impairments towards using measures of activity and participation level as outcomes, including patient reported and patient centred outcomes. The use of impairment measures (as outcomes rather than as baseline descriptors) confuses process and outcome measures. An outcome measure needs to capture the desired end point rather than describing the intervention delivered—that is, even if an intervention has a strong impairment focus, it needs to prove itself by producing a meaningful impact.

There may be divided opinion over whether attention control was the most suitable choice for this study. Uncertainty over the relative contribution of natural recovery versus the early, regular attention provided by therapists or visitors, would have been eliminated by a control group of no contact. However, if therapy had proved more effective, it would remain unknown whether the active mechanism was the therapy or the psychosocial effect of providing attention. An alternative control would have been usual care. Assuming an effect along a

continuum for therapy per se as opposed to attention, with usual care theoretically in between the two ACT NoW groups, our finding of no difference between the two extremes would be replicated when comparing the extreme and midpoint.

Limitations were the absence of descriptive socioeconomic data and the exclusion of people unable to communicate in the English language (as services did not have provision for bilingual speech and language therapists, and the therapists believed that translation or interpretation services were not appropriate for aphasia).

Implications for clinical practice

When the full ACT NoW evidence[18 19] is considered within the context of other recent trials and reviews,[29 17] it is clear that early communication services should be reorganised. Ineffective treatment approaches should be replaced with more promising ones and the latter should be evaluated. There is no suggestion that speech and language therapists should be removed from the early stage of the stroke pathway. The approaches requiring replacement are one to one, impairment focused therapy[18 29 31] and detailed cognitive neuropsychological assessment in the first few months after stroke.[18] The latter was a core component of the ACT NoW intervention and provided only to those allocated to the therapy group. Therapists must continue to distinguish between aphasia, dysarthria, and apraxia of speech and include assessment of the activity restrictions resulting from these often coexisting impairments (such as the pre-randomisation assessment).

Extreme caution is required to avoid over-extrapolation of the evidence leading to damage to vulnerable services for people with high unmet need but potential to benefit. People with communication problems after stroke will continue to need support. Replacement approaches are required, and some services will welcome the justification to develop their activity level and social participatory approaches. These seem to have been used less often in ACT NoW, along with training with a conversation partner and group work. ACT NoW shows that users value and are willing to use support provided early, frequently, and flexibly regardless of whether it is from a therapist or a visitor,[18] so skill mix could be explored to make use of less qualified assistants.

ACT NoW supports a reorganisation of early communication therapy but not a withdrawal of speech and language therapists from the early stage of the stroke pathway. In addition to providing communication therapy, speech and language therapists play an important role in the management of dysphagia (swallowing) that starts during the hyperacute phase and was not evaluated within the trial. Service reorganisation for communication problems could include, for example, a stepped care model, similar to that recently recommended by the Stroke Improvement Programme for psychological support.[34]

Future research

In addition to a trial of a reorganised, early stepped care model of communication therapy versus usual care, future research should evaluate specific interventions that show promise, such as training with a conversation partner and constraint induced aphasia therapy. Certain populations have been badly neglected in previous research such as people with dysarthria, people who were not fluent in English before their stroke, and people living with persisting communication problems years and decades after their stroke. It is important to develop evidence specific to the different stages of the stroke pathway, distinguishing between early and later needs and services. The ACT NoW best practice intervention may have been provided too early in the stroke pathway. The effectiveness of later provision by speech and language therapists remains an important clinical question warranting a clinical trial, likely to be addressed by the recent NIHR Health Technology Assessment Programme's commissioning brief for persistent speech and language problems.

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Contributors: AB, LD, AH, AL, MLR, GP, PT, AV, CW, AY obtained the funding and, together with EP and MW, served on the trial management group. AB was chief investigator responsible for the design and conduct of the study and drafted the reports. AH and PT were acting chief investigators for maternity leave cover. EP was trial manager responsible for day to day management. AY and LD led and reported the qualitative study and economic evaluation respectively. AL and AH led on the development and reporting of outcome measures. AV was the study statistician, designed and analysed the quantitative results, and oversaw their reporting and interpretation. GP facilitated the Research User Group and their involvement in final reporting. CW and MW led on the development of the attention control and contributed to the final report. MLR led the development and reporting of the speech and language Therapy screening and intervention. PT was clinician at the lead NHS site, and led the Research Network which facilitated the study. All authors have contributed to analyses or interpretation of results and drafts of this report and the full HTA monograph from which this paper has been extracted. AB is the guarantor.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: AB, LD, AH, AL, MLR, GP, PT, AV, CW, AY have support from an NIHR HTA research grant for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: This study obtained Multicentre Research Ethics Committee approval (06/MRE03/42) and informed consent or proxy

What is already known on this topic?

Many people survive their stroke with lifelong restrictions on their ability to communicate because of impaired speech (dysarthria) or language (aphasia)

Despite a firm consensus that speech and language therapy is beneficial after a stroke, clinical effectiveness remains unknown, cost effectiveness untested within a trial, and service provision is highly variable and often poorly resourced

Early intervention by speech and language therapists may improve functional communication and quality of life for survivors and carers

What this study adds

Providing more frequent contacts with speech and language therapists or with non-therapist visitors in the first four months after stroke is feasible and acceptable to service users with impaired communication

Functional communication improved over six months for both groups, plausibly due to natural recovery and repeated practice of everyday communication with a therapist or visitor

There were no added benefits of contact with a qualified therapist in the first four months after stroke compared with a non-therapist

consent was obtained from each participant before randomisation. Site-specific and NHS Trust research and development approvals were also obtained.

Data sharing: Technical appendix, statistical code, and dataset available from the trial statistician at andy.vail@manchester.ac.uk. Data sharing consent was not obtained, but the presented data are anonymised and risk of identification is low.

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Tables

Table 1| External validity of eligible stroke patients who participated in study compared with those who declined. Values are numbers (percentages) of patients unless stated otherwise

Characteristic	Participants (n=170)	Eligible but declined (n=272)
Male	95 (56)	145/270 (54)
Mean (range) age in years	70 (32–97)	72 (31–95)
Aphasia,* total:	153 (90)	238/247 (88)
Severe	98 (64)	131 (55)
Dysarthria,* total:	66 (39)	104/239 (44)
Severe	35 (53)	54 (52)
Severe overall communication problem:		
Impairment level	116 (68)	151/245 (62)
Activity level	87 (51)	139/235 (59)
Dysphagia	87 (51)	135/252 (54)

*Measured at the level of impairment.

Table 2| Baseline characteristics of 170 adults with stroke who participated in comparison of speech and language therapy (intervention) and unstructured social contact (control). Values are numbers (percentages) of participants unless stated otherwise

Characteristic	Control (n=85)	Intervention (n=85)
Mean (range) age in years	70 (40–92)	70 (32–97)
Male	46 (54)	49 (58)
Diagnosis:		
Aphasia only	53 (62)	51 (60)
Dysarthria only	8 (9)	9 (11)
Both	24 (28)	25 (29)
Mean (SD) impairment rating:		
Aphasia	1.9 (1.1) (n=77)	1.9 (1.2) (n=76)
Dysarthria	2.5 (1.1) (n=32)	2.2 (1.2) (n=34)
Either impairment severe*	58 (68)	58 (68)
Communication activity rating:		
Mean (SD)	2.2 (1.2)	2.3 (1.3)
Severe	47 (55)	40 (47)
Dysphagia present	47 (55)	41 (48)
Overall disability score†:		
Mean (SD)	10.7 (7.3)	12.7 (7.2)
Mild (score 18–20)	22 (26)	36 (42)
Moderate (score 11–17)	22 (26)	17 (20)
Severe (score 0–10)	41 (48)	32 (38)

*Stratification factor in the randomisation routine. Severe=score of 0–2 on communication activity scale of the Therapy Outcome Measure.
†Based on the 10 item modified Barthel Index, which gives a score out of 20.

Table 3| Details of delivery of the six therapy components among the 81 adults with stroke who received the speech and language therapy intervention. Values are percentages (numbers) of participants

	Therapy component					
Group or subgroup	**Assessment**	**Information**	**Communication materials**	**Indirect contact**	**Direct contact**	**Carer contact (n=73)**
All (n=81)	100 (81)	78 (63)	54 (44)	84 (68)	100 (81)	96 (70/73)
Diagnosis:						
Aphasia (n=72)	100 (72)	79 (57)	57 (41)	83 (60)	100 (72)	97 (62/64)
Dysarthria (n=33)	100 (33)	78 (26)	39 (13)	85 (28)	100 (33)	93 (27/29)
Communication problem:						
Severe (n=37)	100 (37)	86 (32)	65 (24)	81 (30)	100 (37)	97 (33/34)
Mild or moderate (n=44)	100 (44)	70 (31)	45 (20)	86 (38)	100 (44)	95 (37/39)

Table 4| Detailed breakdown of the specific activities included in the "direct contact" component of the speech and language therapy received by the 81 adults with stroke in the intervention group. Values are percentages (numbers) of participants

	Specific activities					
Group or subgroup	**Impairment**	**Functional**	**Conversation practice**	**Goal setting**	**Work set for review period**	**Other***
All (n=81)	93 (75)	67 (54)	60 (49)	86 (70)	30 (24)	85 (69)
Diagnosis:						
Aphasia (n=72)	92 (66)	65 (47)	60 (43)	85 (61)	32 (23)	85 (61)
Dysarthria (n=33)	97 (32)	61 (20)	61 (20)	85 (28)	27 (9)	85 (28)
Communication problem:						
Severe (n=37)	92 (34)	70 (26)	65 (24)	81 (30)	24 (9)	84 (31)
Mild or moderate (n=44)	93 (41)	64 (28)	57 (25)	91 (40)	34 (15)	86 (38)

*Other activities such as counselling, computer use, joint therapy.

Table 5| Primary and secondary outcomes (at six months) for adults with stroke who participated in comparison of speech and language therapy (intervention) and unstructured social contact (control). All outcomes are adjusted for the intended stratification criteria: site, diagnosis and severity of impairment at baseline. Values are means (standard deviations) unless stated otherwise

			Difference	
Scale	**Control**	**Intervention**	**Mean (95% CI)**	**P value**
TOM	3.0 (1.6) (n=72)	3.3 (1.4) (n=81)	0.25 (–0.19 to 0.69)	0.27
COAST	73 (18) (n=50)	71 (18) (n=67)	–1 (–7 to 6)	0.85
Carer COAST	62 (18) (n=59)	62 (21) (n=70)	0 (–7 to 7)	0.91
COPE:				
Negative	23 (3.2) (n=58)	24 (3.5) (n=67)	0.6 (–0.6 to 1.9)	0.34
Positive	13 (2.4) (n=57)	13 (2.5) (n=68)	–0.0 (–0.9 to 0.9)	0.96
Support	11 (3.2) (n=57)	12 (3.3) (n=65)	0.4 (–0.7 to 1.6)	0.47

TOM = Therapy Outcome Measure, COAST = Communication Outcomes After Stroke scale, COPE = Carers of Older People in Europe.

Figures

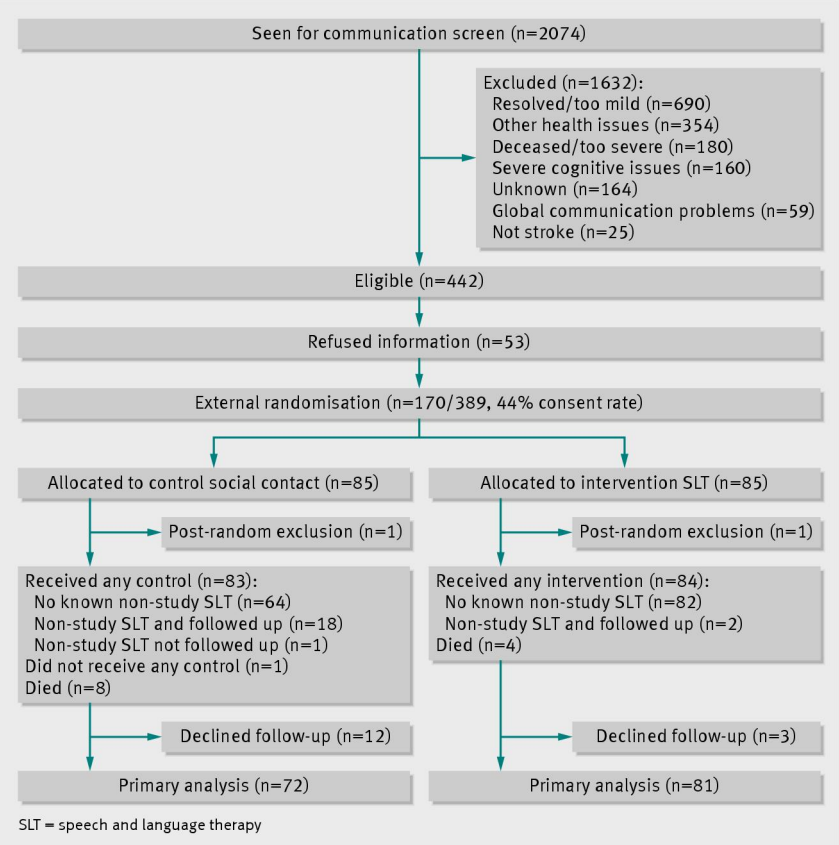

Fig 1 Participant flow through study

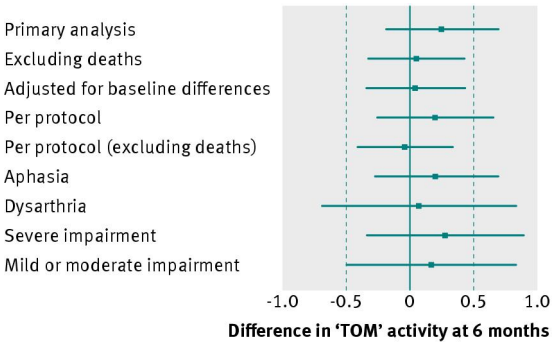

Fig 2 Sensitivity and subgroup analyses for the primary outcome