Early, well-resourced communication therapy following a stroke

Clinical effectiveness, cost-effectiveness and service users' perceptions of early, well-resourced communication therapy following a stroke: a randomised controlled trial (the ACT NoW Study)

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Executive summary

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Background

After a stroke, around one-third of people experience persisting problems with aphasia or dysarthria, limiting their ability to communicate through speech, writing or gesture. This restricts everyday activities and social participation, has adverse psychological effects and negatively impacts on families. Early, regular and intensive therapy may capitalise on brain plasticity, augmenting the natural recovery observed in the first few months.

The impact of speech and language (SL) therapy for this population is unknown owing to an absence of robust research evidence. In 2002, the UK's National Institute for Health Research (NIHR) identified the need to evaluate the clinical effectiveness and cost-effectiveness using therapy that was likely to be feasible for routine NHS delivery and comparing this with an attention control (AC), i.e. patient contact but not specific therapy.

Aim

The ACT NoW (Assessing the effectiveness of Communication Therapy in the North West) study was commissioned by the NIHR Health Technology Assessment programme and began with a feasibility study followed by a definitive study of the clinical effectiveness, cost-effectiveness and service user and carer views of an *early* well-resourced flexible communication intervention delivered by SL therapists, compared with an equivalent amount of contact but not therapy provided by employees badged as 'visitors'. This aimed to examine whether there is an added benefit of early SL therapy over and above a combination of natural recovery and receiving regular empathic attention.

Design

Extensive feasibility work was completed (2004–6), including the development of novel outcome measures. The definitive study (2006–10) consisted of a multicentre, parallel-group randomised controlled trial (RCT), economic evaluation and qualitative study. Randomisation was by an independent trials service. Primary analysis compared groups on 6-month outcomes using an intention-to-treat approach. Cost-effectiveness, cost-effectiveness acceptability analysis and net benefit analyses were used to relate costs and outcomes and explore the value for money of SL therapy, including a survey to determine societal preferences for waiting time and outcomes. The qualitative study used individual interviews with a subset of trial participants to explore service users' and carers' perceptions of process and outcome. Collaborative working partnerships with two groups were central to the design and conduct of this study: a research user group of service users ('the RUG') and a visionary group of NHS SL therapists willing to take on this challenging study.

Setting

The study was based in 12 NHS stroke services in England. Recruitment took place during the inpatient phase. Interventions were delivered across the stroke pathway (hospital and community).

Participants

The NHS SL therapists screened over 2000 people admitted with stroke with possible communication problems and considered one-fifth to be eligible for the trial on the grounds that they were likely to benefit from the research intervention. Exclusion criteria were pragmatic (out of area, unable to communicate in English) or clinical [therapy deemed unsuitable (e.g. pre-existing dementia, learning difficulties) for end-of-life care, serious health (including cognitive) problems, global communication problems or, alternatively, communication problems resolved or likely to without intervention].

One hundred and seventy people were randomly allocated to SL therapy (85) or AC (85), a consent rate of 44% of those invited. RUG-developed, aphasia-friendly consent materials proved useful in maximising trial participation. Participants ranged in age from 32 to 97 years (mean 70 years) and 56% were men. Almost all had aphasia (90%), 39% had dysarthria and 29% had both. Half were classified as having a severe activity restriction (disability) in terms of their baseline communication, suggesting that the sample included the full range from mild to severe. Half had dysphagia (impaired swallowing).

Some people declined follow-up, resulting in 81 and 72 cases, respectively, available for analysis in the SL and AC groups. The economic evaluation examined data from the trial participants in addition to a survey returned by 278 members of the public. Twenty-two trial participants and 10 carers took part in the qualitative study. Carers also participated in the RCT ($n = 135$). They were typically female family members in the same household, not in paid employment and were younger than the stroke participants.

Intervention and control treatments

The SL therapy was a consensus-based, best practice, flexible intervention developed by NHS SL therapists for delivery in usual care settings, but better resourced. This allowed commencement as soon as clinically indicated and, if required, up to three contacts per week for up to 16 weeks, following participants across their stroke pathway. Adherence to the therapy manual was ensured through inspection of written records, observation of delivery and regular peer group meetings.

The study found that therapy was delivered as intended, flexibly tailored to individual need and on average started 2 weeks after stroke, involved 22 contacts (18 hours) delivered over 13 weeks, in both hospital and community settings. Half of the activities coded were direct intervention. Forty-two per cent of contacts were delivered by therapists of Band 7/8. Therapists sometimes felt that it was too early for an individual to engage intensively and 43% were referred for continuing NHS SL therapy after the study.

Attention control was offered at the same intensity by employed visitors who did not provide therapy or any communication strategies. 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 manual allowing everyday activities (e.g. conversation, TV, music), but visits were mostly led by participants. Visitors were monitored to ensure adherence to the protocol.

Main outcome measures

The primary outcome was functional communicative ability 6 months post randomisation, rated on the activity subscale of the Therapy Outcome Measure activity subscale (TOM) by a blinded independent SL therapist. Secondary outcomes were participants' perceptions of their own functional communication and quality of life on the Communication Outcomes After Stroke scale (COAST); carers' perceptions of participants' functional communication using the first 15 questions on the Carer COAST; carers' own quality of life with the relevant five questions from the Carer COAST; and carer 'well-being' using the Carers of Older People in Europe (COPE) Index. Serious adverse events (SAEs) were recorded (deaths, further stroke, readmission to hospital). For the economic evaluation participants completed the European Quality of Life-5 Dimensions (EQ-5D) health status questionnaire and service use data were collected from medical records at 6 months and from carers. Preferences for different outcomes of communication therapy and willingness to wait for therapy were measured by a discrete choice survey completed by members of the public.

Results

External validity was good. Those who participated were similar in their measured characteristics to those who declined. Internal validity was also good. The control group had more disability at baseline but this was adjusted for in sensitivity analyses.

Speech and language therapy services struggled with staffing the intervention but overall succeeded in providing the intended (early but flexible) intervention at an average amount that was higher than most NHS services. Most importantly, they provided continuity by following participants across the stroke pathway, whereas in usual care they would be placed on waiting lists following transfer to the community. There was high uptake of both therapy and control visits by service users. This was slightly lower for the latter, reflecting patient choice; however, an adequate control was provided. An observational comparison of TOM activity scores at baseline and 6 months suggested a clinically meaningful level of improvement in functional communication of 0.8 points [95% confidence interval (CI) 0.6 to 1.0 points] regardless of group allocation.

Primary analysis estimated a difference of 0.25 (95% CI –0.19 to 0.69) points on the primary outcome (TOM) in favour of SL therapy. Sensitivity analyses suggested that this estimated difference was due to the imbalance in baseline severity and the imputation of values for deaths. Per-protocol analyses rejected a possible dilution of therapy from the 18 control participants who rejected their allocation and received some NHS SL therapy. These findings appear robust and exclude the possibility of a clinically significant difference of 0.5 on the TOM in either direction. There was also no evidence of an added benefit of SL therapy on any of the secondary outcomes, including patient- and carer-reported measures. There was no statistically significant difference in SAEs between the groups [odds ratio of 0.42 (95% CI 0.16 to 1.1)]. Although SAEs were less frequent in the therapy group, they were rare (15 vs 7). Subgroup analyses (by aphasia

vs dysarthria or by level of severity of communication impairment) produced no evidence of a differential subgroup effect.

The likely cost-effectiveness of therapy was at the upper end of the acceptable willingness-to-pay thresholds of the National Institute for Health and Clinical Excellence. However, there were several limitations to the economic evaluation and primary and sensitivity analyses indicated a high level of uncertainty, suggesting that it is not possible to conclude whether therapy is more or less cost-effective than AC.

The qualitative study found that, regardless of whether they saw a visitor or an SL therapist, participants highly regarded this experience, which made a positive impact on their lives. The amount of contact and the interpersonal skills/personal qualities of the person providing it (visitor or SL therapist) were identified as important drivers for recovery that built confidence and developed a positive mood. Users believed that an important mechanism for recovery of communicative ability and growing awareness of residual disability was repeated practice of everyday communicative activities with a professional who showed empathy and interest in their individual needs. Carers expressed strongly positive views about the support that survivors had received, whether from the visitor or SL therapist. They identified the importance not just of regular contact, but of that contact coming from someone outside of the survivor's family/social milieu. The outsider provided interaction and communication opportunities that challenged the person they cared for in ways they could not because it forced an engagement with the unfamiliar. Carers did not identify any primary benefit to themselves, but rather secondary benefits from seeing the survivor make progress.

Conclusions

The ACT NoW study provides robust evidence and a definitive answer to a clinically important question, with good generalisability of its findings. Functional communicative ability at 6 months had improved by a clinically meaningful amount for people in both groups. However, there was no evidence of an added benefit of early communication therapy from SL therapists for people with communication disability or their carers over and above that from AC and natural recovery, when both were provided at a higher level than in typical standard practice. Therefore, there is no evidence to recommend enhancing the provision of early communication therapy by a qualified SL therapist over and above usual care, and the evidence suggests that the latter should be reorganised.

To determine whether the benefits were due to therapy rather than time with a therapist, both groups were offered early and well-resourced time. Service users valued the early and frequent contact from professional visitors/therapists outside of their family and friends who showed interest in their individual needs. These impacted positively on their confidence and mood, providing repeated practice of everyday communication. In terms of clinical implications, the study did not evaluate the early role of SL therapists after stroke. Much of SL therapists' early workload is for the assessment and treatment of dysphagia and in usual practice communication and swallowing are managed together. We evaluated one aspect (communication therapy), and only after a diagnosis had been made and provided to the user, family and multidisciplinary team (MDT), thereby precluding conclusions about the value of diagnosis by an SL therapist.

Less definitive were the results on adverse events and the economic evaluation. There remains the possibility that therapy reduced the rate of deaths, further strokes and rehospitalisation and this may have warranted further research had a mechanism been established (i.e. had therapy improved communication), which it was not. Early enhanced SL therapy for communication is

likely to be cost-effective only if decision-makers are prepared to pay ≥£25,000 to gain one unit of utility. However, uncertainty over cost-effectiveness is of no practical concern given the lack of evidence of clinical effectiveness.

There may be divided opinion over whether AC 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 no-contact control. There were two good reasons for not commissioning this. First, if therapy proved more effective (as most people expected) it would remain unknown whether the active mechanism was the therapy or the psychosocial effect of providing attention. Second, it is highly unlikely that a no-contact control trial would have been feasible given ethical concerns and lack of equipoise for clinicians and potential participants.

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.

Recommendations for research

Research should assess a reorganised SL therapy communication service that uses a stepped care model of intervention considering skill mix and timing. SL therapists' early role could be around diagnosis, communicating this to the user and MDT and supervising assistants for regular visits similar to those provided for the AC group in ACT NoW. Intervention would later step up to direct SL therapist contact for those with persisting need and include the part of the stroke pathway referred to as Life After Stroke. Usual care by NHS SL therapists would be an appropriate comparator.

Further research should investigate whether the ACT NoW SL therapy was delivered too soon in the stroke pathway, by evaluating its effectiveness with a chronic clinical population, those with persisting communication problems months and years post stroke. There is huge unmet need in this population yet considerable uncertainty about service delivery and an understandable tendency to assign scarce resources to those in the first 6 months of recovery. A future study would challenge the unlikely but sometimes cited suggestion that recovery is only possible in the short term.

Specific promising interventions should be subjected to RCTs, for example conversation partner training. Therapy for people with dysarthria is a neglected area of stroke rehabilitation research, warranting investigation. Aphasia research must be generalisable to the target population, including people without English as their first language.

Future economic evaluation needs to find ways of capturing valid baseline EQ-5D data from acutely ill and communication-impaired participants and of ensuring sufficient resources to chase missing data from incomplete or inaccessible NHS records.

Trial registration

This trial is registered as ISRCTN78617680.

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