Clarification of conclusions from the ACT NoW trial

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An article by Alex Leff and David Howard in the November issue of *Nature Reviews Neurology* (Stroke: Has speech and language therapy been shown not to work? *Nat. Rev. Neurol.* 8, 600–601)¹ discusses our recent article published in *The BMJ*.² We are saddened that Howard, a member of the ACT NoW Trial Steering Committee, is critical of the trial and welcome the opportunity to respond. We have some concern that therapists unfamiliar with the original publications^{2–4} or with randomized trial methodology may be misled by the debate. Leff and Howard focus on secondary questions and do not acknowledge that the first imperative for an evidence base is to establish whether an intervention is effective.

Leff and Howard raise three concerns. First, they query the control over constituents of both interventions. Speech and language therapy (SLT) is, as they acknowledge, a complex intervention that varies according to an individual's needs. In the ACT NoW trial, therapists agreed upon a range of SLT activities and tailored their intervention within that range to the perceived needs of each patient. A trial of a 'one-size-fits-all' therapy would have attracted justifiable criticism. For the control group, 'visitors' were trained and monitored to ensure that they did not deliver anything considered as therapy; they certainly did not provide conversation therapy—a promising technique that merits further clinical research.

Second, the dose of SLT was queried. Leff and Howard suggest the naive view that 'therapy' constitutes only direct contact, and dismiss the five other components selected by participating therapists. Standard NHS care is stated as involving 8 h of SLT—less than the 9 h of 'direct contact' and the 18 h of broad intervention delivered in ACT NoW. Notably, these times were shorter than the

total offered, reflecting choices made by service users. The Cochrane review of SLT for aphasia warns of patient drop-out from high intensity interventions.⁵ Service commissioners are unlikely to agree that an average of 18 h is homeopathic. Our findings have relevance to current service provision whereas commissioners may not be able to respond to a trial delivering 100 h of therapy.

Finally, the issue of 'absence of evidence' versus 'evidence of absence' was raised. Leff and Howard are correct: evidence showing absence of effect cannot be inferred from a statistical significance test. They fail to note, however, that our inference was correctly based on the confidence interval. *The BMJ* continues to exercise stringent statistical refereeing of articles prior to acceptance.

We have been painstaking in drawing appropriate conclusions from the evidence provided by ACT NoW, specifically that this form of SLT offered at this intensity and duration at this time after stroke was no more effective than attention control for enhancing functional communication or any other outcome, including patients' and carers' own perceptions of effect.^{3,4} We do not extrapolate from our evidence to conclude that SLT is no better than inactivity, or that it would be no better than attention control if given at different times, durations or intensity.

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Competing interests

The authors declare no competing interests.

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