Seizure 2001; **10**: 625–627
doi:10.1053/seiz.2001.0651, available online at http://www.idealibrary.com on IDEAL®

Personal view: Randomized controlled trials in epilepsy specialist nursing: the seduction of content by form

STEPHEN BROWN

Developmental Disabilities Research & Education Group, Plymouth Postgraduate Medical School, UK

Correspondence to: Professor Stephen Brown, DDREG, Unit 10, Bodmin Business Centre, Harleigh Road, Bodmin PL31 1AH, UK. *E-mail*: stephen.brown@cornwall.nhs.uk

Research into the effectiveness of epilepsy specialist nursing needs to take into account a number of factors, which have not been adequately addressed in previous studies. Nursing outcome measures are different to medical ones and it is inappropriate to confuse these. Specialist nurses affect the whole culture of a service, and their impact on service quality may go beyond that of their individual patient contacts. Thus randomized studies within a service that already has specialist nurses may not give valid results. Some service users will benefit more from direct contact with a specialist nurse than others, and people who give informed consent to take part in randomized controlled trials might not be representative of those who would benefit most from specialist nurse access. The stampede for level one evidence risks failing to address the issues properly by overvaluing research process (form) against its appropriateness (content), yet there remain great opportunities for good quality research in this area.
© 2001 BEA Trading Ltd

Key words: epilepsy; specialist nursing; clinical trials.

It has been pointed out elsewhere in this issue[1] that it is inappropriate to use 'medical' outcome measures such as seizure frequency as the main criteria for evaluating nursing interventions, and that use should be made of nursing-based outcomes instead. Although it is obviously incorrect to draw conclusions from studies that use the wrong outcome measures, it seems this point has not been sufficiently addressed in the evaluation of research. The recent Cochrane Review[2] could be given as an example. However, there are other aspects of research design that have also not been adequately addressed up to the present.

It is generally accepted that nurses starting in newly created epilepsy specialist nurse posts take a while to develop the most effective ways of working. It takes time to acquire office space, information technology and educational resources. Something else that takes time but is crucial to the epilepsy specialist nurse role is the development of a certain degree of personal networking within the organization, and also beyond it, for example in primary care or with local social care and educational establishments. At the recent Liverpool ILAE conference the view was expressed that such a process may take up to year. It is therefore inappropriate to start a clinical trial on day one of a nurse specialist's appointment in a newly created post, although this apparently happened in one randomized controlled trial (RCT). The value of such a study must be extremely limited, and adds very little to the body of knowledge about epilepsy specialist nursing. However, in the stampede for acquiring a certain type of 'evidence' a perverse regard is given to such work purely on the basis that it was an RCT.

I would like to suggest that research effort take into account three underlying assumptions. They are of course themselves susceptible to challenge and to study.

(1) **Specialist nurses affect the whole culture of a service, and their impact on service quality may go beyond that of their individual patient contact.**

Those who work with specialist nurses note that the training of non-specialist nurses and of other professions in primary care teams and in social care situations is strengthened.

 © 2001 BEA Trading Ltd

Some doctors' time is freed up for other things that the doctors might not otherwise do. If new service users are randomized to 'nurse' or 'no nurse' within a service that already has a specialist nurse service, then the 'no nurse' group will still be seen in a service that has a specialist nurse service. This may well reduce differences between groups. A further problem is that many epilepsy units that have specialist nurses operate an open access policy whereby people with epilepsy are encouraged to self-refer. People randomized to 'no nurse' in such situations would have nothing to prevent them making contact directly. How to deal with these statistically is a challenge (see below).

(2) **Some service users will benefit more from direct contact with a specialist nurse than others, and**

(3) **People who give informed consent to take part in RCTs might not be representative of those who would benefit most from specialist nurse access.**

Service users eligible for inclusion in an ethically conducted trial would have the role of the epilepsy specialist nurse explained to them. They might then be asked, 'will you consent to enter a clinical trial in which you have a 50% chance of seeing a specialist nurse and a 50% chance of not seeing one?' They would also have to be told that if they didn't enter the trial they would have a 100% chance of seeing a specialist nurse if they wished. One might argue that people who felt they might need to see a nurse would be less likely to agree to enter a study. On the other hand, people who felt it didn't matter much whether they saw a nurse or not would be more likely to agree to enter, having nothing to lose. Furthermore, people who feel they might benefit from direct contact with a specialist nurse might indeed be more likely to do so than those who are indifferent. Such self-selection for inclusion in clinical trials would therefore tend to distort outcomes by minimizing differences between the groups.

A more appropriate way of conducting a RCT would be to take two complete services, one of which had epilepsy specialist nurses and one that did not, and randomize new patients between them. There would still be some blurring of boundaries if the specialist nurses took part in training of residential care staff in the community and staff in primary care settings, as this might have an impact on subjects allocated to the control 'no-nurse' group. But, even if two such services could be found covering the same catchment area, there would still be the issue of what sort of people would give informed consent to participate. In this case, the question would be, 'do you wish to take part in a study where you have a 50% chance of being allocated to a service where there are nursing staff trained in the subject who have specialist skills in dealing with your problems, and a 50% chance of being allocated to a service where the nursing staff do not have these skills?' This is really a rhetorical question, although the answer might depend on what alternatives are available for people who do not take part in the study. One way of boosting recruitment would be to have the service that has specialist nursing in it only available to people taking part in the trial and randomized to it. There are clearly serious resource problems in setting up such a trial. Since no such trial has been carried out I would suggest that there is *no* suitable evidence at the RCT level of the effectiveness or not of epilepsy specialist nurses.

I was once involved in a failed attempt to partially address some of these issues. There was an epilepsy service (based in what we might call hospital A) with well-established specialist nurses with an open-access self-referral policy in addition to direct referral from medical practitioners. The specialist nurses did not see all people with epilepsy, but anyone who so wished could make contact. Referrals to nurses from medical practitioners came from both within and without the epilepsy service. The nurses also played an important role in training care staff in residential homes, and in working to improve the skills of primary care staff in the community. In the next town there was a district general hospital (B) served by the same neurology team, with similar access to electroencephalogram (EEG), computerized tomography (CT), and magnetic resonance imaging (MRI), but with no epilepsy specialist nurses. Catchment area demographics were similar for hospitals A and B. The only obvious differences between the two services were that one had specialist nurses and the other did not, and that they were in different towns. Although we could not randomize new referrals to one or other service, I thought there might nevertheless be value in a parallel group design taking equivalent cohorts of new patients recruited in the same time period, and follow them up using a variety of appropriate measures. There would still be some potential contamination of the 'non-nurse' hospital B group for three main reasons. Firstly, with A's open access policy, some patients from B nevertheless found their way to A's specialist nurses. Secondly, some GPs in hospital B's catchment area used the services of the nurses in hospital A, and thirdly, paediatric and general medical consultants in hospital B sometimes circumvented the neurology service by directly referring to A's specialist nurses. In order to

know how to deal with these 'crossover' patients in the statistical analysis, I consulted with a specialist in evidence-based medicine and trial design. The whole concept that I outlined was, I was told, of no value because there was no randomization. Only randomization would do. Randomization is king. Because of the geographical distance between A and B and the difficulty of travelling for patients, we obviously couldn't take all referrals to both hospitals and randomly allocate between the two. Instead, the only reasonable way forward was to drop hospital B completely and randomly allocate people referred to hospital A to see, or not to see, the specialist nurse. I pointed out that not everyone needed referral to specialist nurses. Easy, came the reply, randomize to 'see nurse if you want to' vs. 'don't see nurse'. But, I said, we have an open access policy; some people randomized to 'no-nurse' might still see the nurses of their own accord. Also, usual treatment would mean having nurse access. The trial wouldn't be one investigating the potential value of a new service component that would otherwise not be available, it would be one of the effect of cutting out a bit of the service already available. Surely that would raise ethical, let alone recruitment, problems? In that case, I was told, people randomized to 'no-nurse' group could of course make contact with a nurse if they wished *but for statistical reasons they would have to be treated as if they had not seen a nurse, on the basis of intention-to-treat analysis*. After speaking to the expert, therefore, the best design for an RCT evaluating the effectiveness of specialist nursing meant that people could be randomized to one of two groups. In the first group they could see a specialist nurse if they wanted to, but didn't have to. In the second group they didn't have to see a nurse unless they wanted to. It seemed obvious to me (but not to the expert) that these two intervention packages were essentially identical, and yet apparently if there were no real differences between outcomes in the two groups, this would suggest epilepsy specialist nursing had nothing special to offer. The study of course never got done. I was left musing on the triumph of form over content. An RCT was just the thing because it was an RCT and for no other reason. This took precedence over the use of appropriate subjects, intervention packages and outcome measures. As Nigel Molesworth is reported to have said, 'Ebm-ers swank much about there hierarky of evidens, from meta-analysis at top to anecdot at bottom, and say Your study is below RCT, so is No Good chiz[3]'.

We also lack solid evidence for the value or effectiveness of *doctors* in epilepsy teams, certainly at the RCT level. There are however, interesting reports from non-randomized studies showing that appropriately trained health workers who are not doctors can diagnose and treat many people with epilepsy[4–6]. Suppose we were to use the same rules for evaluating the role of doctors as has been applied to the value of specialist nurses? We might well be drawn towards a negative or at best equivocal, conclusion. Could we justify advising health commissioners of the value of increasing the establishment of neurologists? Alternatively we could come to our senses. All that is being proposed is that professionals who work in a specialist service have training in, and develop skills in, that specialism. There is a rich seam to be mined in investigating the effectiveness of various cadres of the service in carrying out the different service tasks (diagnosis, management of drug regimes, and counseling and other therapies). If we wanted to take it up, there is an opportunity to do something useful.

REFERENCES

1. Greenhill, L., Betts, T. and Pickard, N. The epilepsy nurse specialist—expendable handmaiden or essential colleague? *Seizure* **10**: 615–624.
2. Bradley, P. and Lindsay, B. Specialist epilepsy nurses for treating epilepsy (Cochrane Review). In: *The Cochrane Library*. Oxford, Update Software, 2001.
3. Petticrew, M. Down with EBM! *British Medical Journal* 1998; **317**: 1720–1721.
4. World Health Organization, *Initiative of Support to People with Epilepsy*. Geneva, World Health Organization, 1990 (WHO/MNH/MND/90.3.
5. Adamolekun, B., Mielke, J. K. and Ball, D. E. An evaluation of the impact of health worker and patient education on the care and compliance of patients with epilepsy in Zimbabwe. *Epilepsia* 1999; **40**: 507–511.
6. de Jong, J. T. A comprehensive public mental health programme in Guinea-Bissau: a useful model for African, Asian and Latin-American countries. *Psychological Medicine* 1996; **26**: 97–108.