



Physiotherapy as a clinical science: The role of single case research designs

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EDITORIAL

Physiotherapy as a clinical science: The role of single case research designs

To an outside observer (a clinical psychologist), it appears that there is increasing pressure on physiotherapists (and other therapists) to evaluate, and hence justify, their interventions. Some of the pressure comes from purchasers of health care in today's market-led world. Some of the pressure comes from within the profession, reflecting a desire to ensure that physiotherapy maintains and develops its position as an applied clinical science. Indeed, it is surely a mature profession which has the confidence to scrutinise its methods, to identify in an objective and scientifically credible way which treatments truly benefit patients and which are likely to be a waste of time, effort and money. The clinical practice of all therapists is guided to a large extent by their own experience with patients as well as the experience of those who have taught them. However, an 'apprenticeship' model of clinical development is acceptable only if the treatments handed down through successive generations of therapists have at some point been systematically evaluated. As Riddoch and Lennon (1991, p. 4) noted, 'it is not ethical to administer unproven therapies', and as Beswetherick (1994, p. 60) argued, 'The physiotherapy profession needs to have a better understanding of the relationship between intervention and outcome . . . where interventions are shown not to be beneficial we must stop their practice'. Personal recommendations from satisfied customers, be they the patient or the referring doctor, may ensure a steady flow of business, but they should not be sufficient for any profession which seeks to be an applied science and thereby offer more effective treatments.

Having emphasised the need to evaluate treatment, it is necessary to consider the methods available for doing so. There are no *easy* options when it comes to doing good clinical research. There are, however, a range of methodologies

which enable the interested clinician to evaluate his or her work. The two most prominent methodologies for evaluating treatment outcomes are randomised control group designs and single case experimental designs. Both aim to measure the effect of treatment, while at the same time controlling for any other variables that might be responsible for the change in the patient. The major difference between group designs and single case designs (apart from the number of patients in the study!) is the means by which this experimental control is achieved. The choice as to which method to use is not a question of which is more scientifically credible; both are, when properly applied, respected in the wider scientific community. Rather, the question should be which method is more appropriate to the research question being asked and to the situation in which the research will be carried out.

If the question being asked is, 'Should all patients with a particular problem be given a particular treatment?', then a randomised controlled trial is the most appropriate approach. However, as I shall highlight later, single case methodology also has a role in addressing this question. Randomised controlled group designs evaluate treatment effects by comparing two groups of patients, one of which receives the treatment under scrutiny and the other does not. The methodology is at its clearest in drug trials which utilise a randomised double-blind placebo control trial in which patients are randomly allocated to either the treatment group which receives the active drug or the control drug which receives the placebo. The placebo controls for the possibility that receiving a 'treatment' that participants may believe to be effective might cause them to experience or report benefits irrespective of the efficacy of the active treatment. The patient and the person administering

the drug are also 'blind' to whether the drug is the active drug or the placebo. Even drug trials are not always truly 'blind', because it may be possible for the patient to determine from the presence or absence of drug side-effects whether or not they are receiving the active drug. When it comes to any sort of behavioural, psychological or physical therapy, it is usually impossible for the patient and the therapist to be blind to whether or not treatment is being applied (see Klaber-Moffett, 1991; Sunderland, 1991; Shapiro, 1989; Riddoch and Lennon, 1991). It is also frequently impossible to have any form of placebo and therefore it may be more effective to compare two sorts of active treatment. With careful planning, it is possible to make the treatments very similar, varying only in terms of the presence of the particular aspect of treatment that is to be evaluated. This may also avoid the ethical difficulty of withholding treatment. A factor that should always be considered is whether the clinical problems as well as the treatment that is applied are really the same for each patient. Too much heterogeneity is likely to dampen the treatment effect in group studies and force the conclusion that a treatment is ineffective, when it is in fact effective, but only in some situations.

Single case experimental designs (which should not be confused with single case studies, which are purely descriptive and have no experimental control) provide a means of answering the research question, 'Does this treatment (or treatments) work with this particular patient (or series of patients)?' Such a question might be asked by therapists who wish to evaluate their routine clinical practice, by therapists who are applying a traditional treatment to a clinical problem to which it has not previously been applied, or by therapists who have developed a new treatment for an 'old' problem. The basic method in single case experimental designs is repeated measurement during the no-treatment baseline (A) phase (or phases) and during the treatment (B) phase. Any results in a simple AB design (baseline followed by treatment) are open to the interpretation that spontaneous recovery and not the treatment itself caused the effect. The way this problem is handled is to use either a

reversal design (in which the treatment is withdrawn and the baseline phase is thus reintroduced, the ABA design) or, alternatively, a multiple baseline design can be used. It is this latter design which is probably most suited to the rehabilitation environment, because reversal designs are frequently not possible (e.g. if a particular manipulation has effectively eliminated a problem, it would be neither possible nor desirable to reinstate the original condition). Farrel (1991) used a multiple baseline across behaviours design when she evaluated the impact of sitting-to-standing exercises on wheelchair transfers and weightbearing exercises on walking backwards. Clearly it would not have been possible to use a reversal design, as it would have been impossible to undo the experience of carrying out the exercises. In the multiple baseline across behaviours design, two or more target behaviours/problems (in this case, wheelchair transfers and walking backwards) are monitored during a baseline phase. Then a treatment (sitting-to-standing exercises) is applied to the first target behaviour/problem (wheelchair transfers), while the second behaviour/problem (walking backwards) continues to be monitored in a baseline phase. In some situations, it is possible simply to use the second behaviour as a control for the possibility of spontaneous recovery (technically this would be termed an 'AB with a control variable' design). However, the more usual method would be to subsequently apply treatment (weightbearing exercises) to the second behaviour/problem (walking backwards). As in the Farrel study, this second treatment may not necessarily be exactly the same as the first treatment, making it possible to evaluate a number of different treatments for various problems, while always controlling for the possibility that either spontaneous recovery or some other non-treatment factor is causing the changes in the patient.

The issue of the generalisability of results to other similar patients is important in any treatment evaluation. If a randomised control group study demonstrates a significant effect of a treatment, then one might feel confident that such a treatment should be applied to patients with the same problem. Nevertheless, it is still important to remember that unless the treatment tested was

always successful, then there will be a number of patients for whom the treatment will not work. Most group studies offer little indication as to why treatments might not work with some patients. An obvious limitation of single case experimental designs is that it is not possible to generalise on the basis of a single case. Nevertheless, if a particular treatment result is replicated in a series of patients, then the generalisability of the result increases over time. Alternatively, the single case experimental study could be followed up by a randomised controlled trial to examine the generality of the findings. Furthermore, the intensive procedures of a single case in which the treatment does not work, afford the opportunity to attempt to tease out the situations where a treatment will work and where one will not work.

Another important issue concerns the interpretation of results and the question of statistical as opposed to clinically significant change (Wilson, 1987). A question that should always be asked when designing research studies, be they group designs or single case designs, is what would represent clinically significant change. It is all too easy to get caught up in the enthusiasm of getting a statistically significant result and lose sight of what the result means in practice. Single case experimental designs have traditionally relied on the assumption that if a treatment effect cannot be seen clearly when the data are graphed, then the treatment is not effective. In an ideal world, treatment effects would always be clear, but of course there are times when data are 'messy', such as when there is considerable variability within baseline and treatment phases. Such variability can make interpretation difficult, but in this situation there are statistical methods which can help. If you find yourself in the rare position of having at least 50 data points per phase, then time-series analysis (see Kazdin, 1984) would be relevant. Most of us engaged in clinical research are more likely to feel lucky if we can collect up to 10 observations per phase. Even in this situation, however, there are techniques which can help identify trends in data, including Tyron's C statistic (Tyron, 1982; Blumberg, 1984) and the various other non-parametric trend tests described by Morely and Adams (1989). All of these techniques are easy to

calculate without the need to be a statistical wizard. Such techniques do not specifically compare treatment with baseline phases, but by applying trend tests separately to each phase one can identify different trends which might be present in each phase (ideally, there would be no trend in the baseline phase and either a downward or upward trend, depending on the measures used, in the intervention phase).

As Bithell (1994) recently noted, clinical psychologists have used single case experimental methodology for some time now, the methods originally being developed to evaluate the effectiveness of behaviour modification programmes. However, since then the methods have been used in a wide range of situations to evaluate a variety of treatments. Clinical psychologists in conjunction with physiotherapists have recently used single case experimental designs in the evaluation of auditory feedback for walking difficulties in a patient with unilateral neglect (Robertson and Cashman, 1991) and improving standing tolerance and posture in a severely brain-injured patient (Alderman et al, 1992). The special issue of this Journal devoted to single case methods (Vol. 7, No. 1, 1991) provided a number of examples of how to apply the methods to clinical problems. Such studies are still few and far between, but it should not be concluded from this fact that such methods are not useful or applicable. Rather, the enthusiastic physiotherapist should conclude that there is plenty of scope for doing interesting and useful studies!

Clinical research in any profession should always begin with a clearly articulated research question. Following that, the design can be chosen, taking into account such factors as the number and heterogeneity of patients available, type of treatment, viability of withholding treatment for any length of time, and frequency with which data could be collected. Any suggestion that the *only* satisfactory method of advancing the clinical knowledge of physiotherapy is by large randomised control group designs is excessively narrow, and likely to discourage clinicians from carrying out and writing up evaluations of their treatment methods. Therapists should be encouraged to be applied clinical scientists and to make evaluation of treatment as routine as thor-

ough assessment. In this way, expertise in a range of research methodologies will develop widely within the profession, the number of publishable research studies will increase, and the profession will benefit from greater confidence in its methods.

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