FACTORIAL TRIALS AS A METHOD OF STUDYING
PHYSIOTHERAPY

FRANCES K. BAINBRIDGE, M.A.P.A.
for
The Associate Study Group

SUMMARY

This article discusses the need for research in the field of physiotherapy, and the difficulties involved in carrying out this type of research. It describes a factorial trial, and the advantages of using it in physiotherapy. The appendix is a letter from a statistician, and discusses some of these advantages in more detail.

THE PROBLEM

Do you ever stop to consider to what extent physiotherapy treatment alters the natural history of your patient's condition? That is, would he gain full recovery without physiotherapy, or do you significantly speed up the process of recovery?

These questions can only be answered accurately by doing controlled studies which compare the rate of recovery and the degree of recovery in patients who have physiotherapy with the rate and degree of recovery in patients who have no physiotherapy.

Some studies of this nature have been done, for instance in the areas of emphysema (Finney, 1967), acute neuritis in leprosy (Hokin, 1968), and muscle atrophy (Stoboy, 1968). However there are many areas of physiotherapy for which we could find no reference to work of this kind.

Another question that arises is, what form of physiotherapy should I use? Should I use heat or cold, would massage or manipulation be helpful, should I give conventional exercises, or should I use Proprioceptive Neuro-muscular Facilitation, or the techniques used by Mrs. Bobath or Miss Rood? How do I know when one of these treatment methods will be more useful than another?

Again, a limited amount of work has been done to try and find answers to these questions (Brewerton, 1966; Hamilton, 1967; Trott, 1968), but in the main physiotherapists apply their treatment methods by a process of trial and error. We form personal opinions about the effectiveness of various methods of treatment, but we do not at present have sufficient opportunity to see if our opinions are supported or contradicted when scientifically tested.

Controlled trials of physiotherapy techniques are not simple (Ritchie, 1966). Firstly, we do not have sufficiently accurate methods of measuring the things we are interested in: muscle strength, tone, pain, sensation, co-ordination, etc. By contrast, in the fields of agriculture and engineering, there are accurate and objective methods of measuring, for instance, the amount of wheat produced, or the amount of distortion in a piece of metal.

Physiotherapists do not have specialised knowledge of research methods and analysis of results, nor are there facilities, finance, or specialised staffs readily available to help us. It is imperative for physiotherapists intending to conduct a clinical trial of any sort to seek a statistician's advice about the structure of the trial so that the results it yields will be valid, and not due to natural variation among patients and therapists. However, organising a trial is very time consuming and cannot normally be done by someone who already has a full work-load.

There is a further problem in the field of physiotherapy research. Because of the high percentage of women in the profession, there is a high turnover of staff. This interferes with the administration of a research pro-
gramme because the treatment given and results recorded will vary to a greater or lesser extent from therapist to therapist. This variation cannot be avoided in a subjective discipline such as physiotherapy.

We have also found that some hospital authorities object to control groups of patients who receive no treatment, or they have a method of treatment which, in their opinion, is the best and they are not prepared to change their policy in the interests of research. Often there is a lack of the co-operation between various hospital departments which would make the carrying out of research projects easier, and a lack of adequate routine recording by physiotherapists which would make retrospective analysis possible.

PLANNING A FACTORIAL TRIAL

The Associate Group of the Victorian Physiotherapy Post-Graduate Society decided to investigate the possibilities of itself conducting a trial. We were initially interested in demonstrating the effectiveness of cold therapy in the treatment of osteoarthritic knees; that is, we would compare the progress made by patients who received cold therapy as part of their physiotherapy treatment programme, with the progress of patients who had an identical treatment programme with heat therapy instead of cold therapy.

We invited a statistician, Mr. J. R. Bainbridge, Senior Lecturer in the Computer Centre at Monash University, to discuss with us the problems involved in ensuring that the results obtained would be valid.

There are numerous variables among patients which influence the degree of improvement possible and the speed of the improvement; for instance, the initial severity of the condition, the patient’s general medical condition, his age, weight, enthusiasm to improve, occupation, and so on. Therefore, the groups of patients receiving variations in treatment would have to be large, to increase the likelihood of these variables being evenly distributed in all groups, so that any difference in the results obtained from a particular group will be due to the different treatment and not to the fact that a larger number of patients in that group than in other groups had a greater or a lesser chance of showing improvement.

In addition, one is not entitled to assert that heat is better than cold, or vice versa, unless observation shows it to be better in a range of circumstances, for example, heat and passive movement is better than cold and passive movement; heat and massage is better than cold and massage; heat alone is better than cold alone, and so on.

A factorial trial overcomes these two difficulties. The treatment programme is divided into several different techniques, and these techniques are applied in as many different combinations as possible. For instance, the treatment of an osteoarthritic knee could be divided into heat or cold, massage, passive movement, and exercise. There are eleven different ways of combining these four techniques. One combination includes all four techniques, five combinations include three techniques, and five combinations include two techniques. Some of the combinations are:

- heat or cold and massage,
- massage and passive movement,
- heat or cold and massage and exercise.

If we add to this the use of each technique by itself, and one patient who receives no treatment, we have sixteen different treatment programmes. That is, to use each treatment programme once would involve sixteen patients. If each programme were used twice, it would involve thirty-two patients and quite useful results should be obtained. Doubling the size of the trial again to sixty-four patients would demonstrate even minor differences between the treatment programmes.

We discussed the problem of giving no treatment to one out of sixteen patients and the statistician suggested we use a half replication of the above design. That is, we only use eight of the treatment programmes, selecting all the ones that include heat or ice, and eliminating the patient who has no treatment. Then useful results can be obtained from sixteen patients.

(For an explanation of why a factorial trial enables useful results to be obtained from a relatively small number of patients, see the appendix to this article.)

The statistician suggested that we include another knee condition in this trial, using the same treatment programmes for these patients.
as we use for the patients with osteoarthritis. This brings the total number of patients in the trial to thirty-two.

For ease of analysis, the trial was designed for eight physiotherapists to treat four patients each. Their treatment programmes were carefully selected, so that each physiotherapist has two patients with osteoarthritis and two with a more acute condition. Two of each therapist's patients have cold therapy and two have heat therapy, two have massage and two don't, two have passive movement and two don't, and two have exercise and two don't.

Analysis of the results obtained will show:

(a) The effect of each treatment method when used by itself and when used in combination with the other treatment methods.

(b) The effect of each treatment method on each knee condition.

(c) The degree of difference between individual physiotherapists, provided this is not so great as to make the whole experiment invalid, which is unlikely.

This type of trial eliminates many of the problems formerly encountered in conducting trials in physiotherapy.

It reduces:

(a) The necessity of objective testing methods.

(b) The degree of accuracy needed in taking measurements.

(c) The number of patients required.

It eliminates the importance of variations among patients, and the importance of variations in the way physiotherapists assess and treat their patients.

Factorial trials have not, so far as we know, been used in medical research before, and it remains to be seen whether valid results are indeed obtained.

**Conclusion**

In conclusion, we feel that research in the field of physiotherapy is the profession's greatest need, if it is to establish itself as a responsible, co-ordinated body. But as we have pointed out, under our present conditions the difficulties are such that we can expect only a very limited amount of research to be done. If more research is to be done, staff and finance must be provided specifically for research purposes.

**Appendix**

The size of an experiment is a guess beforehand. The necessary size depends upon how large the effect you are trying to measure turns out to be. It depends also upon how large the errors you are trying to circumvent turn out to be. Finally, it depends upon the degree of certainty you are prepared to accept that the observed result could not be due to error.

There are some rough guides. If error is large and difficult to control, yet easy to detect—this is expected in the present case—you are unlikely to get a satisfactory result in much under thirty-two observations. At the other end of the spectrum only very complex situations, or cases where one is trying to detect very small or rare effects, should require more than about one hundred and twenty-eight observations. It is desirable to plan an experiment in "blocks" which can be added to if circumstances show this to be desirable. We do this sometimes with houses also!

Factorial experiments, particularly those employing a number of factors each at two levels (for example, with and without massage, exercise, etc.), lend themselves particularly well to this block structure and expansion. In addition, every test result contributes to information on every factor so that with five factors one gets information out of thirty-two tests for which one hundred and sixty tests would be needed if one factor at a time was varied, other things being equal. By careful arrangement of the factors it is possible to include as a "factor" some of the disturbing variation. This means that this variation has been removed from the "residual error" which may interfere with conclusions. The wanted conclusions are based on patients treated by the same therapist, so differences between skill in different therapists do not confuse the effects of treatment. Other sources of disturbance can be partially removed by associating them with "block" differences which are ex-

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cluded in the analysis. For example, “social class” may in many obscure but real ways impinge on the efficacy of treatment. It so happens that there are social class, work class, political class segregations in our cities, and as a result, a geographical grouping into blocks helps to reduce errors of this kind.

The net result is that if full advantage is taken of the blocking structure of the factorial experiment, it usually transpires that the “residual unallocated error” is a good deal smaller than in other types of experiment. Consequently, more precise results are obtained from an experiment of a given size, or a smaller experiment will prove adequate.

However, the proof of the pudding is always in the eating. One plans the pudding using all one’s care, knowledge, and experience. One carries out the mixing, and cooking, and serving, with equal care and skill. But—how will it taste between the teeth?

References


