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Correspondence

CLINICAL TRIALS AND BEHAVIOUR THERAPY

DEAR SIR,

It would seem time that attention was devoted to the problem of why certain ideas or research findings immediately provoke attention whereas others are neglected for years.

Foulds' article, "Clinical Research in Psychiatry", (*Journal*, April, 1958), which pointed out that many more uncontrolled trials of drugs reported successful treatment than did controlled trials, provoked widespread interest, and was universally interpreted as indicating that uncontrolled trials allowed the clinician's subjective feelings to enhance the true therapeutic effect of the drug, whereas the controlled trial presented an unbiased accurate finding. Such a view, salutary at the time, has now developed into what might be regarded as a sightless veneration of the double-blind trial.

A contribution to the necessary corrective view by Free (1962) has evoked little attention. He pointed out that the false positive result—the Type I error—is not a serious one in good research. It is discarded as soon as other workers fail to replicate it. The Type II error—the false negative result, the "failure to find a lead which does 'in fact' exist" may be far more harmful. Not only may it discourage further research, it can lead to complete cynicism concerning what appears to be the application of scientific method to psychiatric research. Clinicians today are beginning to demonstrate such an attitude in response to the reports of apparently methodologically correct double-blind drug trials of which some conclude that a drug is therapeutically active, the rest that it is not.

In his article, Free pointed out that in controlled trials one should commence with a consideration of how much better the treatment under investigation needs to be than the placebo or comparison treatment to produce a statistically significant difference between the groups given the different treatments. This decision determines the number of patients who need to be investigated if the experiment is to have a reasonable chance of demonstrating such a difference.

To quote Free:

"For example, a new drug is expected to provide 60 per cent. satisfactory responses and a placebo only 40 per cent. satisfactory responses if the regimens are studied in a very large patient population. If this is true, one should like to compare these regimens in a smaller sample and show statistically ($P < \cdot 05$) that the drug is better. If one used 35 patients per regimen, one stands only a 50-50 chance of demonstrating a statistically significant difference. Whereas, if one studies 105 patients per regimen, one has a 90 per cent. chance of attaining a statistically significant difference. These odds might be looked upon as 5 successful studies out of 10, or 9 successful studies out of 10, but in practice only one study is run and the decision is made from just that group of patients. Perhaps this suggests one reason why the current literature records so many negative findings." When one considers that the number of drug trials which investigate over 200 patients can be numbered on the fingers of one hand, the moderation of this conclusion can only be admired. Wechsler *et al.*, (1965) and Lipman *et al.*, (1965) have advanced further reasons why the controlled trial as commonly practised is heavily biased against demonstrating therapeutically active drugs to be so.

It now appears that research in behaviour therapy is to be bedevilled by similar methodological formalism. Marks and Gelder (*Journal*, July, 1965) published a retrospectively controlled trial of a form of behaviour therapy with 20 treated phobic patients and 20 controls. In regard to the main phobic symptoms, 9 patients were much improved with behaviour therapy and remained so at one year follow-up, as against 5 of the controls. However, as "the proportion of patients showing each degree of improvement did not differ between the two groups on any occasion (χ^2 test)", Marks and Gelder paid no attention to this finding, even though Cooper (1963) had reported a similar one. His was also a retrospectively controlled trial of 10 phobic patients treated with behaviour therapy and 10 controls, and he found that in regard to their main phobic symptom 4 patients treated with behaviour therapy were much improved at the end of treatment and 5 at one year follow-up, as against 1 and 2 respectively of the controls.

Gelder and Marks (*Journal*, March, 1966), in a controlled prospective trial of phobic patients, have now reported that 4 of 10 patients treated with behaviour therapy were much improved as regards their main phobic symptom, as against 2 of the controls. They do not comment on the consistency with which this finding has appeared in a series of trials, and in fact do not on this occasion give data which allow it to be determined how the much

improved group did on follow-up. They appear to have changed their criteria for rating improvement, thus rendering comparison of their present results with previous ones less valid. Yet, with these small numbers studied, only the pooling of data from several studies can lead to meaningful findings. Their somewhat pessimistic conclusions with regard to the form of behaviour therapy they practise may be justified, as they may feel that the degree of improvement in the extra 2 patients or so in 10 who have their main phobic symptom much improved is not worthwhile. But as this appears their most constant and important finding, some space could surely be given to discussing it in addition to that taken up by the many graphs of the vicissitudes over time of mean scores of various symptoms of these two small groups of patients.

N. McConaghy.

School of Psychiatry,
University of New South Wales,
Sydney.

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PSYCHOGENIC DYSPAREUNIA

Dear Sir,

Dr. Haslam's treatment of psychogenic dyspareunia (*Journal*, March, 1965, p. 280) seems to be well worth trying, especially in cases that have failed to respond to other methods. A patient I have recently been treating clearly illustrates most of the points mentioned by Dr. Haslam in his paper.

Mrs. A. was unable to tolerate any attempt at intercourse. There was a history of her having been examined p.v. at the age of thirteen and this had been painful. Her first attempt at intercourse had produced a similar pain, and since then she had been too terrified to try again. She had received a wide range of unsuccessful treatments, including the combination of "psychotherapy" and digital exploration described by Dr. Mackie (*Journal*, August, 1965, p. 774) In addition to the dominant fear of intercourse, she was also afraid of such activities as travelling, meeting people and answering the telephone.

In our Department, over a period of 14 months she was seen almost every week and a fair trial given to the following treatments: hypnosis; systematic desensitization using relaxation and a hierarchy of imagined situations (both general and also related to intercourse); dilatation and incision of perineum under anaesthesia; amytal abreactions; and drugs such as amytal, chlordiazepoxide, phenelzine, imipramine and Potensan. All this therapeutic endeavour resulted in a marked lessening of generalized anxiety and the development of an ability to relax in practically any situation. Wolpe's method of systematic desensitization using relaxation was largely responsible for this improvement. However, intercourse remained totally impossible.

It was then decided to use Dr. Haslam's method. The first three sessions took twenty minutes each, and it was observed that the maximum spasm occurred with the passage of the first bougie, notwithstanding that this was always the smallest of each series. At the fourth and fifth sessions the patient passed the bougies herself, being more able to tolerate the larger sizes this way. Intercourse became completely satisfactory and normal after these five treatment sessions, which took place over a period of four weeks.

It is suggested that graduated glass or plastic bougies allow a closer approximation to the intercourse situation, and combined with relaxation responses this method offers the best chance of a cure for cases of psychogenic dyspareunia.

A. B. Masters.

Department of Psychological Medicine,
Sharoe Green Hospital,
Preston, Lancs.