

## Leading Article

# EMPIRICALLY GROUNDED CLINICAL INTERVENTIONS: COGNITIVE-BEHAVIOURAL THERAPY PROGRESSES THROUGH A MULTI-DIMENSIONAL APPROACH TO CLINICAL SCIENCE

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**Abstract.** The current emphasis on Evidence Based Medicine (EBM) is both welcome as a bid to improve the empirical foundations of clinical practice and a cause for concern because it has the potential to distort the scientific approach that has underpinned the development of cognitive-behavioural approaches. It is suggested here that EBM needs to be seen in context; that is, as an approach that almost exclusively focuses on just one of the dimensions that have been and are crucial to the further development of Cognitive-Behavioural Treatments (CBT). EBM is particularly well suited to the development of Biological approaches to treatment, where treatments (and treatment development) are largely atheoretical. However, different considerations apply to CBT, where validated theory and linked research studies are key factors. It is suggested that relationship to evidence in CBT is best conceptualized in terms of Empirically Grounded Clinical Interventions. The parameters of such an approach are considered in relation to the Scientist Practitioner model that is prevalent in the field.

*Keywords:* Evidence-based medicine, Empirically Grounded Clinical Interventions, cognitive-behavioural treatment, scientific progress, theory, experimental research.

## Introduction

Evidence-based approaches to mental health have been presented as a notable innovation (Chambless & Ollendick, 2001; Sackett, Rosenberg, Gray et al., 1996), with the undoubted potential to revolutionize the care and treatment of those suffering from psychiatric and psychological problems. It is encouraging that those who worked solely on the basis of clinical judgement and personal prejudices are now being encouraged to take a more systematic approach, and to base the choice of treatment on what is defined as “gold standard” outcome evidence. However, this development can also be viewed with concern because we

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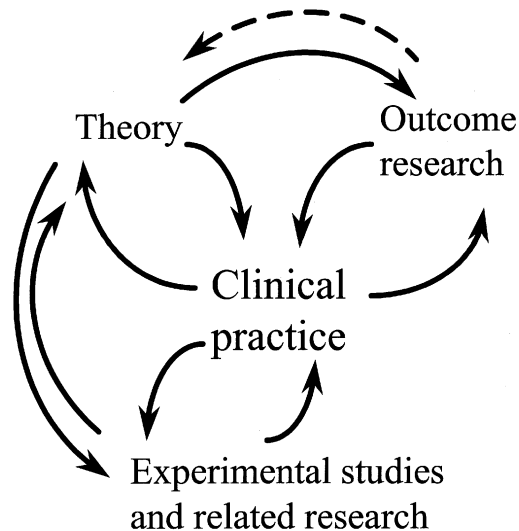
now face the risk that advances made through science will be overtaken by the unthinking application of scientism. The overly narrow evidence-based approach emphasizes the supremacy of randomized controlled trials of treatment outcome. In addition, it seeks to aggregate studies over time and populations and makes prescriptive recommendations based on meta-analyses. Whilst it can readily be agreed that outcome data are of considerable importance, the idea that such data (and inflexible and potentially inappropriate ways of selecting and reducing it) are of *paramount* importance is not consistent with the scientific approach that has typified the meteoric development of cognitive-behavioural approaches over the past 30 years, and which has made it the treatment of choice for many psychological problems. An evidence-based establishment has arisen, and it is not at all clear that the way in which this seeks to deal with research is necessarily the most appropriate one (or that these are always the most appropriate people to do so).

The risk inherent in the current practice of evidence based mental health is that the field will degenerate into a parody, a kind of one-dimensional science, and there are signs that this has already occurred to some degree. Similar concerns, with a slightly different emphasis, have been voiced in North America (Rosen & Davison, in press). What is described in this present article is the model of clinical science that has underpinned (and should continue to underpin) cognitive behavioural approaches to the understanding and treatment of psychologically-related problems.

Cognitive behavioural therapy (CBT) was an evidence-based approach to mental health problems long before the term “evidence-based” was coined, but it was and is much more than the current meaning of the term. CBT is best described as a set of empirically grounded clinical interventions, carried out by clinicians who seek to operate as scientist-practitioners (Barlow, Hayes, & Nelson, 1974; Shapiro, 1961). Understanding why there is a need to be wary about uncritically adopting current EBM approaches requires an understanding of the dimensions of clinical science that have underpinned the development of Empirically Grounded Clinical Interventions in CBT.

### **The dimensions of clinical science: Empirically Grounded Clinical Interventions**

A pattern of systematically interlinked factors (Figure 1) has been the basis for the development and refinement of first Behaviour therapy and then Cognitive-behaviour therapy. The requirement for such an approach is increased rather than diminished by the progress made so far in our understanding and treatment of psychological disorders. The scientist-practitioner/clinical science approach has clinical practice at its heart. Clinical practice is both the target of our work and a source of information and inspiration that drives other aspects of the process of empirically grounded clinical practice. A good grasp of the phenomenology of the psychological problems we deal with is a necessary pre-requisite for deriving and refining theories of such problems. Such clinically grounded theories in turn inform the way in which we seek to understand the phenomenology. The scientists who have had an enduring influence on current theoretical views in psychological therapies (such as Sigmund Freud, Joseph Wolpe, Aaron T. Beck, Jack Rachman, David Barlow and David M. Clark, to name but a few) have all been clinicians who listened to and sought to understand what their patients were telling them as both a starting point and as a continuing part of their research efforts. Clinical practice and theory also jointly inform the focus of outcome research, in that their combination indicates what type of interventions should be used and



**Figure 1.** Factors involved in Empirically Grounded Clinical Interventions

what kind of process and outcome measures are likely to yield good information. Note also that cognitive-behavioural approaches have tended to focus on the development of treatments for problems where existing approaches have been ineffective, weak or inefficient. Identification and analysis of factors underlying the *failure* of treatments (and of treatment failures) has been and continues to be a stimulus to the development of new ideas concerning how psychological problems are understood and how they might better be treated (Foa & Emmelkamp, 1983). CBT for problems such as panic disorder, OCD, psychosis and hypochondriasis are prominent examples of the unfolding of this principle. Contrary to widely held beliefs, the link from treatment outcome back to theory is extremely weak. The effectiveness of a particular treatment tells us nothing about the mechanisms involved in a particular disorder. For example, the effectiveness of SSRIs in the treatment of a particular disorder does not (and cannot) indicate that such problems are caused by serotonin deficiencies. The impact of data on treatment effectiveness is greatest when treatments are *not* effective. Thus, if one is committed to the view that a particular belief is a key factor in maintaining a type of anxiety disorder, and a treatment is successful in changing that belief but does not improve the disorder, the theory is wrong. Thus, relatively ineffective interventions can disprove the importance of both theory and treatment elements, whilst the effectiveness of treatments and treatment packages does not strengthen the theoretical basis of that treatment. There are some other ways in which treatment trials *can* inform theory, and that is when measures of mechanism are included in such trials. For example, Clark et al. (1994) demonstrated that a theoretically important factor (misinterpretation of bodily sensations measured at the end of treatment) predicted *relapse* at the one year follow-up.

If treatment studies are not the main mechanism by which theory and clinical practice can be advanced, we must consider the importance of experimental studies and other research. Experimental studies, designed to evaluate theories of psychopathology and general psychological mechanisms, have both helped to refine these theories and directly or indirectly

suggest clinical interventions. Note that many of the procedures we use clinically today are grounded not in randomized controlled trials of therapy packages, but rather in experimental studies that focus on two main issues. Firstly, studies that identify the factors likely to be involved in the maintenance of a specific disorder, symptoms and clinical presentations, and which could therefore usefully be modified in the course of treatment. Such experimental studies vary from very precise laboratory investigations that seek to dissect an aspect of psychopathology in ways related to the phenomenology of the problem (Clark & Teasdale, 1982) through to field experiments in which the controls are less precise but ecological validity is built in (Rachman, de Silva, & Roper, 1976; Salkovskis, Clark, Hackmann, Wells, & Gelder, 1999). This type of strategy has been described in considerable detail elsewhere (Clark, 1999). A further contribution is made by other research, including work on individual differences and epidemiological studies.<sup>1</sup> Secondly, it is possible to draw upon experimental studies that clarify how specific procedures or factors can be used in order to optimize treatment interventions. Such studies often (but not invariably) involve investigations in non-clinical samples. To take one example of many, research into memory suggests that much of the information transmitted during a discussion taking place over the period of an hour is likely to be lost to recall. However, the use of an audiotape that is listened to after the discussion will improve recall of the information. It is most unlikely that anyone will ever conduct a study of CBT done either with or without the patient receiving an audiotape (or conduct the multiple studies needed for meta-analysis) because of statistical power issues. However, it is simply not needed. Experimental research into recall and repetition provide the empirical basis that justifies the incorporation of audiotapes into existing treatment procedures. Experimental studies, fuelled by clinically derived “hunches”, theories of psychopathology or derived from basic psychology, can and do help introduce innovative features into practice. We have known for many years that these experimental studies are most commonly studies involving randomized group evaluations. Indeed, where such studies of psychological mechanisms or psychopathology are considered by evidence based medicine, they are carefully examined according to the “gold standard” of randomized controlled trials. If not consistent with the technology of RCTs, they are dismissed as “uncontrolled”. This represents a serious failure of understanding; the technology of single case experimental design (Hersen & Barlow, 1976) allows the creative application of a range of controls for threats to internal and external validity in ways that simply cannot be encompassed within the current practice of EBM. Such work is to be encouraged rather than criticized.

Theoretical development through experimental studies, and a better understanding of mechanisms involved in possible treatment elements, together with consideration of existing outcome studies will, once in a while, mean that there has been sufficient development of a treatment approach to justify the setting up of appropriately powered high quality randomized controlled trials comparing the outcomes of previously established with newly refined developments (or entirely new approaches). Many aspects of cognitive behavioural therapy are now following this “leapfrog” pattern, resulting in a rapid evolution of clinical practice, posing problems for those who wish to combine older with newer work, and problems of dissemination of treatment strategies (Barlow, Levitt, & Bufka, 1999). We must not, then,

<sup>1</sup> For simplicity of exposition, the term “Experimental studies” is intended to imply non-experimental investigations of this type in the remainder of this article.

make the mistake of assuming that conducting the RCT (or meta-analysing a collection of them) is somehow the real science; the factors described here suggest that great caution is needed when considering current Evidence Based Medicine. EBM contributes as one aspect of a broader interlocking approach to therapy, Empirically Grounded Clinical Interventions. ECGIs allow the clinician the flexibility to go where EBM will not. For example, is it not always clear that the results of randomized controlled trials can be generalized to “complex” cases, such as patients with comorbid problems excluded from previous clinical trials. Indications of the most appropriate interventions can be derived from understanding the psychopathology of each problem and their most likely commonalities derived from experimental and other studies and information from single case experimental designs such as replication series.

#### **Further heretical thoughts: Limitations of the evidence-based approach**

There are important limitations to the evidence-based approach to mental health. Some are acknowledged, some not. It is almost an article of faith in some circles that evidence-based approaches provide the best and most objective way of helping clinicians to deliver the most effective treatment for any given patient. In one vision of this, the doctor enters the diagnosis and patient characteristics on a computer system, which indicates what the treatment of choice would be. The computer operates on the basis of an “expert system”. This means that it would use an algorithm derived from the best available evidence, particularly systematic reviews. The problems of systematic reviews and meta-analyses are beyond the scope of the present article, but there can be little doubt that the shortcomings are considerable, especially in fields where the data are sparse and/or rapidly evolving, as well as the problems posed by the interpretations made by the authors of such work. In addition, it is difficult to reconcile an “expert system” approach with the current drive to enhance patient autonomy and empowerment. A system that empowers the individual patient to choose to participate in the decision making process, and which includes but is not confined to the medical outcomes assessed in meta-analyses, is needed (Hope, 1996). Prescriptive treatment (which is not synonymous with CBT, despite some assertions to this effect) carries further problems. It is reasonable to receive treatment on the basis of best evidence, but when such treatment fails or has incomplete effects, it is unhelpful if the clinician is not aware of this and/or unwilling to offer novel or emerging variants of the best practice.

How then, to account for the explosion in EBM in mental health? The answer appears to lie in the widespread adoption of medical model in psychiatry. Evidence Based *Medicine* as presently advocated is well suited to biological treatments, which are almost without exception initially “discovered” rather than developed from an understanding of the nature of psychiatric problems. This has been the case for treatments such as ECT and antidepressant medication. Once a potentially effective treatment has been identified, it can then be delivered in standardized ways and standardized doses, in the same way as antibiotics or statins. Metanalysis is then an appropriate (and extremely useful) tool for such standardized interventions. There is also little or no scope for further development of this intervention other than by dose adjustment or developing compounds with slightly different side-effect profiles. Given the atheoretical nature of the initial development of biological treatments, almost nothing is known about the mode of action, so enhancement and advancement of clinical treatment through improvements in understanding the mechanisms involved is

almost never a possibility. These factors make the present version of EBM well suited to those branches of biological psychiatry that choose to ignore phenomenology and the psychological understanding of psychological problems.

### **Conclusion: CBT embraces a multi-dimensional approach to science and clinical practice**

Evidence Based Medicine may be appropriate as a way of making coherent sense of dozens of studies in which thousands of patients are administered identifiable doses of medication, or in treatments such as most psychotropic medications, which have been stumbled upon rather than developed and refined. It seems unlikely that it will ever be appropriate to exclusively consider the management of psychosocial problems in this way; to do so would be to endorse a one-dimensional approach to science. CBT has thrived because, from the earliest days, it has been both evidence based *and* empirically grounded. This grounding is in a range of different types of evidence, including but definitely not confined to randomized controlled trials. The unique strength of CBT lies in the past and future development and application of Empirically Grounded Clinical Interventions, applied by clinicians who have adopted a scientist-practitioner approach (see Rosen and Davison, in press, for a further critique and discussion of the importance of being guided by Empirically Supported Principles of change, ESPs). Empirically Grounded Clinical Interventions as outlined here are responsive to a range of influences. The main emphasis of such an approach is: (i) Treatment *principles* are based on a scientifically framed and evaluated theory of the maintenance of the specific problem. (ii) Treatment *procedures* are based on the best evidence about (a) the treatment package and (b) components that may be added or modified. Both *principles* and *procedures* are refined through a combination of clinical observation, theoretical and experimental development. The social and cultural context should form part of the understanding of EGCI. Such treatments are not only flexibly grounded in a range of evidence, but also make the gathering of evidence an intrinsic part of clinical practice. It is important to emphasize that none of what is discussed here is new, but some is in danger of being lost.

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