Psychotherapy for patients with complex disorders and chronic symptoms

The need for a new research paradigm[†]

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Background A clear distinction has been made between efficacy and effectiveness in relation to the methods of evaluation of new psychological treatments in psychiatry. Efficacy trials target patients with relatively pure conditions, who may not be representative of the patients who are usually referred for psychological treatment in a clinical setting. Few studies have explored the benefits of psychotherapy in patients with complex disorders and enduring symptoms.

Aims To explore the rationale for the distinction between efficacy and effectiveness, particularly in relation to outcome studies of patients with complex and enduring disorders.

Method A narrative review with examples drawn from the literature, and an illustration of a recent naturalistic outcome study which combines features of both efficacy and effectiveness.

Results Studies of patients with complex and mixed disorders can be designed so that they retain internal validity, but also have external validity and are relevant to clinical practice.

Conclusion Studies which evaluate psychological interventions should be carried out in populations of patients clinically representative of those who are likely to receive the intervention, should it be shown to be of benefit.

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[†]See editorial, pp. 93–94, this issue.

Since the beginning of the 1980s, there has been an explosion in the development of psychotherapy research, particularly in the fields of cognitive and behavioural psychotherapies, but also, in a less dramatic way, of therapies that have an interpersonal orientation. Psychotherapy outcome research has been focused on the treatment of patients with specific diagnostic conditions, such as major depressive disorder. Therapies have been tailored or fine-tuned to make them 'condition-specific'.

This paper examines the rationale for this approach to research into the outcomes of psychotherapy, and, in particular, the distinction that is usually made between efficacy and effectiveness. It argues that studies of psychotherapy should have clinical relevance, and should be targeted towards definable clinical populations or characteristics of patients, rather than diagnostic conditions. An outcome study which has just been conducted in Manchester, involving patients with chronic complaints with multiple symptoms, will be described in order to illustrate some of the main points of the argument. The paper will consider the potential role of psychotherapies with an interpersonal focus in the treatment of patients with complex and enduring symptoms.

THE DRUG METAPHOR IN PSYCHOTHERAPY OUTCOME RESEARCH

The drug metaphor of the double-blind randomised controlled trial has been used as a template for the evaluation of psychotherapy over the last 20 years, although it is virtually impossible to design a double-blind study of psychological treatment. The widespread use of randomised controlled trials (RCTs) in psychotherapy research, however, has had several important benefits. First, the empirical credibility of research into psychological treatment has been enhanced, as evidence from clinical trials is currently accepted by the scientific community as the 'gold standard' of evidence about treatment efficacy. Second, very specific and efficacious treatments have been developed for specific diagnostic disorders (Klerman *et al*, 1984; Elkin *et al*, 1989; Frank *et al*, 1991; Shapiro *et al*, 1994). Third, an emphasis has been placed upon evaluating treatments in terms of measurable 'hard' outcomes (usually symptoms), as opposed to more subtle, less reliable indicators such as 'gaining greater insight'. Finally, the results from some RCTs have challenged well-established clinical assumptions which have been shown to be erroneous (e.g., the suitability of certain kinds of patients for psychotherapy).

Treatment manuals are now used regularly in psychotherapy outcome research, to ensure that therapists adhere to specific prescribed therapeutic interventions. The writing of manuals has forced therapists to describe and commit to paper what they think they actually do. This exercise focuses the mind, and has resulted in greater clarity concerning the supposed therapeutic ingredients of different therapies; and it has also been beneficial in relation to training (Binder, 1993; Crits-Christoph *et al*, 1995; Calhoun *et al*, 1998).

When manuals were first used in outcome research, they were written with the intention of standardising therapies already in use in clinical practice, i.e., therapies that had some clinical validity. Manuals were used to enhance the internal validity of the study, but at the cost of clinical flexibility and effectiveness. However, it has become more usual to write manuals from scratch for new theoretical approaches, before testing out these new therapies in a clinical setting. The trend has been to develop more and more specific therapeutic techniques and theoretically 'pure' therapies, which are then tested upon highly selected groups of patients (Silverman, 1996).

EMPIRICALLY VALIDATED TREATMENTS

State-of-the-art RCTs of psychological treatments usually involve the testing of a 'manualised' 'pure' therapy for the treatment of a single disorder as defined in ICD–10 or DSM–IV (World Health Organization, 1992; American Psychiatric

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Association, 1994), in a group of patients who meet strict – often restrictive – study criteria. The therapists who deliver the treatments are usually highly skilled and experienced. Therapies that have been tested in this fashion have been termed "empirically validated or supported therapies" (Chambless & Hollon, 1998). Two task forces in the USA, the American Psychological Association Task Force on Psychological Intervention Guidelines (1995) and the Task Force on Promotion and Dissemination of Psychological Procedures (1995), have drawn up lists of therapies which have been shown to be of proven efficacy in relation to individual DSM-defined diagnostic conditions. It has been suggested that the therapies on these lists should be used in preference to non-proven treatments (Chambless *et al*, 1996).

In the UK, Roth & Fonagy (1996) carried out a comprehensive, balanced and authoritative review of the benefits of psychotherapy for mental health. Like the American task forces, they marshalled evidence for the benefits of psychotherapy according to individual diagnostic groups. However, for each condition they outlined the limits of current knowledge, they estimated the strength of the conclusions that could be drawn from existing empirical literature and they sought to identify future research goals.

GENERALISABILITY OF OUTCOME RESEARCH TO CLINICAL PRACTICE

Although the actions of these two task forces and the review by Roth & Fonagy (1996) have strengthened the position of psychological treatments, particularly in relation to pharmacological interventions (Clarkin *et al*, 1996), the move has also caused much disquiet (Persons & Silberschatz, 1998), mainly because of the tension between research and clinical practice. In particular, few clinicians believe that the results from efficacy studies can be easily generalised to clinical practice (Seligman, 1995; Garfield, 1996; DeRubeis & Crits-Christoph, 1998), and when this has been tried, the results have often been disappointing. In a clinical setting, even in primary care, most patients have more than one major psychiatric diagnosis (Sherbourne *et al*, 1996; Olfson *et al*, 1997). In addition, comorbidity is associated with high rates of social disability and persistence of symptoms (Ormel *et al*, 1994). Yet there are very few studies that have explored the benefits of psychotherapy in patients with complex disorders and enduring symptoms, as most efficacy studies specifically exclude such patients. In addition, pharmacological agents have been shown to be as effective, if not more effective, than most psychological therapies for the treatment of common, 'diagnostically' pure psychiatric disorders. Most clinicians will use pharmacological agents as a first line of treatment for these disorders, reserving psychological treatments for those patients who either decline pharmacotherapy or fail to respond. This results in the rather peculiar situation where most psychological treatment studies target patients who in clinical practice would be treated with drugs, and exclude patients who in clinical practice would be offered psychological treatment.

Other important concerns relate to the wide variations between patients, and to the therapist's skill (Beutler & Clarkin, 1990; Barber *et al*, 1996). In any psychological efficacy study of a specific diagnostic condition, there is a basic assumption that patients who share the same specific cluster of symptoms (e.g. major depressive disorder) represent a homogeneous group. While they may be homogeneous in terms of their symptoms, there is little other evidence to suggest that they are similar in terms of personal attributes, interpersonal function, personality traits, previous life experiences, social circumstances and attitudes to psychological treatment. All these factors, and more, may be of some importance when conducting a psychological treatment and may significantly influence outcome (Garfield, 1996), yet they are assumed to be irrelevant for the purposes of the study.

Although the introduction of therapy manuals led to a significant advance in research into psychotherapy, it has resulted in an emphasis on the importance of specific techniques, as opposed to the skill of individual therapists. It is well established, however, that some therapists, using the same form of therapy, produce consistently better outcomes than others (Beutler *et al*, 1994). Thus, one of the most powerful determinants of response to psychotherapy is the skill of the therapist, rather than the specifics of a particular therapy. This potentially important impact on the results of any psychological treatment study is rarely addressed.

Another reason for tension between research and clinical practice is that therapists rarely actually practise what they say they do. Free from the constraints of a study, psychotherapy is usually self-correcting; if a particular strategy appears not to be working, the clinician may adopt a different approach. Thus, although training therapists to use manuals may reduce differences between therapists during a study, therapy conducted in a trial setting may not be representative of the way therapies are conducted in the National Health Service.

In response to these issues, there is a move to design better, more flexible treatment manuals (Goldfried & Wolfe, 1998) which will provide therapeutic guidelines for the therapist when confronted with in-session dilemmas, or a breakdown in the therapeutic alliance (Calhoun *et al*, 1998). These important factors are often missing from traditional therapeutic manuals.

Although research into the outcome of psychotherapy is fraught with many difficulties, including its relevance to clinical practice, it should remain a high priority. Many clinicians still assume that the therapy that they provide is effective, but are not willing for it to be tested empirically. Without controlled outcome research, therapists may be delivering treatment which at best is ineffective and at worst harmful (Frazier & Mosteller, 1995). Equally, potentially beneficial therapies may lose their credibility because of a failure to submit them to scientific scrutiny.

Linking outcome research to clinical practice

There are three possible ways in which the gulf between research and clinical practice can be bridged. The first uses the paradigm of the 'hourglass model' (Salkovskis, 1995). This envisages a new therapy or technique developed in an experimental setting, and then being tested in an efficacy study; once efficacy has been proven, the clinical effectiveness of the therapy is established through field trials and service evaluations. This model maintains a clear distinction between efficacy (the so-called outcome of a treatment tested in an RCT) and effectiveness (the evaluation of the treatment in clinical practice, usually using a 'before-and-after' design).

A problem with this model, however, is that the therapy is designed and tested in

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relation to subjects with relatively 'pure' disorders. This therapy is then delivered to subjects in the clinical setting who have complex disorders, on the assumption that it will be equally efficacious. Any evaluation in the clinical setting is usually much less rigorous, and rarely involves an RCT. Thus, the *efficacy* of the treatment in relation to the actual group of patients whom it is used to treat in a clinical setting is rarely evaluated.

The second model, often called benchmarking (Parry & Richardson, 1996), involves evaluating the effectiveness of psychotherapy in the clinical setting without recourse to an RCT, using large naturalistic treatment studies. Patients receiving psychotherapy can be evaluated within clinical services, before and after treatment, to determine whether they report an improvement in their symptoms or overall functioning. Databases with large numbers of patients can be developed which can provide valuable data concerning predictors of outcome in relation to psychotherapy, patients' preferences, etc. (Howard *et al*, 1996). Such studies, however, do not address the fundamental question as to whether psychotherapy is better than no treatment at all.

Non-randomised comparisons of treatments are sometimes undertaken in clinical settings. While these studies are usually more powerful in determining outcome than before-and-after designs, they do not address the problems of patients' bias and the effects of selection, inherent in such designs.

The third model involves a new paradigm in psychotherapy outcome research. The distinctions between efficacy and effectiveness are broken down, and instead, the importance of clinical representativeness (in relation to the research) is highlighted (Shadish *et al*, 1997). Randomised controlled trials are conducted in clinical settings with patients who are representative of particular clinical populations, rather than specific conditions defined in the DSM or ICD: for example, patients who fail to respond to drug treatment, or who decline pharmacotherapy, or who have chronic multi-symptom complaints.

Other clinical groups reflecting patient characteristics can also be targeted in this way. These could include 'personal compatibility', or 'patient stage of change' (the degree of the patients' insight and motivation to accept treatment and carry out tasks), which have been studied intensively and with therapeutic benefits in the field of addiction (Prochaska *et al*, 1992). Other markers which could be studied in relation to matching different styles of therapy with different patients are patients' expectations, patients' resistance potential and patients' personality and coping style (Norcross & Beutler, 1997).

As an example of this kind of research, in a prospective study of outcome for depression in relation to different forms of group psychotherapy, patients who had an externalising coping style were found to have improved more than non-externalising patients with cognitive therapy; and, conversely, patients with a defensive coping style improved most using self-directed therapy (Beutler *et al*, 1994).

One of the most interesting developments in this area of research has been the operationalising of interpersonal patterns and their impact on the person's view of self, using the Structural Analysis of Social Behaviour (SASB; Benjamin, 1993). This approach has been specifically used for the study of patients with personality disorder, but can be used for any psychological condition. Instead of trying to match a specific therapeutic approach with a DSM–IV category of personality disorder, an individual is explained in terms of their interpersonal patterns of behaviour and social interactions, built on three orthogonal dimensions: 'the actions and reactions of others', 'the actions and reactions of the self' and 'the internalisation of interpersonal experience in the form of the introject' (how one acts towards oneself).

SASB fosters cumulative, theory-driven research by permitting problem–treatment–outcome congruence. The conceptualisation and measurement of patients' problems, treatment processes and outcome can all be conducted using a common metric (Henry, 1996). SASB permits the researcher to define the nature of the personal pathology and its aetiology, to provide a precise measure of the presenting problems linked to this theory of pathology, to operationalise treatment interventions, to link therapeutic process to outcome both theoretically and empirically, and to measure interpersonal and intrapsychic changes relevant to the aims of therapy in a manner directly linked to the definition of the problem. This approach has considerable benefits for researchers, but it is clinically useful too, as it tilts the focus towards interpersonal models of behaviour, and measures outcome in terms of change in interpersonal patterns, rather than cluster-based diagnoses of symptoms.

In addition to strategies which place a greater focus on clinical problems relevant to both patients and clinicians, there is a need to match therapy interventions with the characteristics of the patients. This is particularly apparent in relation to psychotherapies that focus upon interpersonal relationships as a vehicle of change. Although specific interpersonal therapies (IPT) have been developed in relation to certain diagnostic conditions (such as IPT for major depressive disorder, Klerman & Weissman, 1993), it would seem more logical to try to tailor IPT according to specific kinds of interpersonal problems or maladaptive patterns. Indeed, one of the strengths of IPT may be that they do not have to focus upon particular symptoms, but can be used for patients with multi-symptom complaints, who have a clear underlying interpersonal problem or problems (Roth & Fonagy, 1996).

A research methodology is required that places greater emphasis on the homogeneity of clinical problems, rather than the homogeneity of diagnostic categories. There are already various examples of this research approach in the literature, although funding from research bodies is still mainly directed towards the study of so-called pure diagnostic groups. Linehan *et al* (1991) used a self-correcting non-manualised treatment to great effect for patients with multiple problems chronically liable to self-harm. There are several methodologically sound studies of psychological treatments for somatisation or chronic medical condition (Guthrie *et al*, 1991; Speckens *et al*, 1995; Sharpe *et al*, 1996). These studies have ignored psychiatric classification systems, but recruited patients on the basis of their clinical presentation of somatic complaints. The studies have high clinical validity, as patients were recruited on a consecutive basis from clinical settings, and only patients who had not responded to conventional treatment were recruited.

Economic evaluation of psychotherapy outcome research

This approach has particular merit for the economic evaluation of psychological treatments, where it is imperative that any study should have high clinical validity in addition to a detailed health economic

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evaluation. It is legitimate to assume that psychological treatment approaches, if they are of benefit, will have the greatest economic impact in patients with chronic and enduring problems. Studies that focus upon pure diagnostic groups, and exclude patients with complex disorders or chronic symptoms, may miss the opportunity to demonstrate cost savings.

In the last ten years, health economic evaluation has become an increasingly important outcome in the assessment of treatment interventions, both in the USA (Krupnick & Pincus, 1992; Sharfstein, 1997; Wolff *et al*, 1997) and the United Kingdom (Parry & Richardson, 1996; McGrath, 1994). However, few studies involving psychotherapeutic treatments have been specifically designed to enable detailed health economic analyses to be carried out, and in most, cost reporting has been inconsistent (Gabbard *et al*, 1997).

Psychotherapy is often perceived as an intensive and expensive treatment for mental illness (Healey & Knapp, 1995), yet there is preliminary evidence that it may result in cost savings, primarily through the direct mechanism of a reduction in health care utilisation but also by the indirect effects of increased productivity, when treated patients are able to return to work (Aveline, 1984; Gabbard *et al*, 1997).

TREATMENT OF PATIENTS WITH MULTIPLE SYMPTOMS

As an example of the third paradigm of research described in this paper, I shall describe a recent study which examined the cost-effectiveness of psychodynamic interpersonal (PI) therapy for patients with chronic and enduring mental health symptoms (Guthrie *et al*, 1999). In this study, the distinctions between efficacy and effectiveness were broken down. It was conducted in a clinical setting with patients who were representative of a particular clinical population (patients with neurotic conditions which did not respond to psychiatric treatment), rather than a specific condition as defined in the DSM or ICD. The study has clinical validity and is relevant to both clinicians and researchers. It was conducted with the scientific rigour of an efficacy study, and had a randomised controlled design. A manualised treatment was used, and treatment integrity was maintained by means of regular supervision and adherence to the treatment manual.

Patients were not recruited to the study because they belonged to a particular diagnostic group, but instead because they suffered from chronic neurotic psychological symptoms which had failed to respond to treatment. These are the very patients for whom general psychiatrists would most like to get help from psychological treatment services, yet most are excluded from formal efficacy studies. This group incurs high costs in health service treatment; but if psychotherapeutic treatment were successful it could decrease health care costs.

Consecutive patients who had had psychiatric symptoms for at least 1 year and had been in treatment for at least 6 months without improvement were approached to take part in the study. Patients with organic brain syndromes and psychosis were excluded. Out of 144 eligible patients, 110 entered the study; 34 declined to take part.

The main aim of the study was to determine whether psychodynamic interpersonal therapy plus 'usual treatment' was more cost-effective than 'usual treatment' alone in this group of patients. Detailed health economic profiles on the patients were taken at the start of the study, at the end of the trial period and at follow-up 6 months later.

Psychodynamic interpersonal therapy was formerly known as the Conversational Model of Hobson (1985), and has been described in more detail elsewhere (Guthrie *et al*, 1998). It is manualised, and a rating scale for adherence is available. It has been found to have effects equivalent to those of cognitive–behavioural therapy (Shapiro & Firth, 1987; Shapiro *et al*, 1994) for the treatment of depression, and has also been adapted to treat patients with psychosomatic symptoms (Guthrie *et al*, 1991). It is relatively easy to teach to health professionals and the effects are maintained over at least 2 years (Moss *et al*, 1993). A book summarising the research on the model, and containing an updated manual, is due to be published shortly (Barkham *et al*, 2000).

Patients were assessed on entry to the study, at the end of the trial period (8 weeks) and at follow-up 6 months later. The Syndrome Checklist–90–Revised (SCL–90–R; Derogatis, 1992) and the 36-item Short-Form Health Survey (SF–36; Ware & Sherbourne, 1993) were used to assess psychological symptom distress and health status. Detailed service utilisation and non-treatment costs were recorded for each patient over three specific periods of time: for 3 months prior to study entry, for the intervention period of 8 weeks, and for 6 months after the trial period.

Of the 110 patients who entered the study, 69 (62.7%) were female and the mean age was 41.1 (s.d.=9.8) years. Sixty-eight patients (61.8%) were deemed incapable of work and were receiving state benefit. The median length of the current illness episode for the whole group was 5 years (interquartile range 3–9 years). Patients had been receiving treatment from psychiatric services for a median of 3 years (interquartile range 2–6 years).

The stratification of the patients according to their scores on the SCL–90–R depression sub-scale was as follows: 7 (6.4%) 'mild'; 11 (10.0%) 'moderate'; and 92 (83.6%) 'severe'. There were no significant differences between treatment and control groups on the SCL–90–R, the SF–36 or any of the health economic measures on entry to the study.

At the 6-month follow-up assessment, subjects randomly allocated to psychotherapy showed significantly greater improvement in measures of psychological distress and social functioning than did controls. During the intervention phase of the study, patients in the psychotherapy group had significantly more out-patient appointments than the controls (with each psychotherapy session counting as a formal out-patient session). There were no other differences between the psychotherapy group and the controls on any of the other indices of service utilisation. During the 6-month follow-up period, patients who had received psychotherapy showed a significant reduction in comparison to controls in the following indices of service utilisation: fewer days as in-patients, fewer consultations with the family physician, fewer contacts with the practice nurse, and were prescribed fewer medications. In addition, patients who had received psychotherapy required significantly less informal care from relatives than did the controls. In total, for the subjects who received psychotherapy the cost of health care utilisation was significantly less in the 6 months following treatment compared with controls, and the extra cost of psychotherapy was recouped within 6 months through reductions in health care use (Table 1).

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DISCUSSION

The results from this study are encouraging, and suggest that even very brief psychotherapy (8 weeks) can result in an improvement in psychological symptoms in patients with chronic unremitting psychiatric disorder, and this improvement in turn leads to decreased use of services and savings in cost.

Potential advantages of psychodynamic interpersonal therapy

There are two key aspects of psychodynamic interpersonal therapy which may make it particularly suitable for helping patients with multiple symptoms. First, it is an interpersonal therapy, which means the treatment focuses on the interpersonal problems or conflicts which underlie the presentation of symptoms, rather than focusing on the symptoms themselves. Second, the conversational style, and the emphasis on developing a close working relationship with the patient, are particularly helpful in engaging patients who are ambivalent or wary of psychiatric treatment and who have previously been resistant to any kind of therapeutic endeavours.

Heterogeneity versus homogeneity

The Manchester study can be criticised for the relative heterogeneity of the group of patients, who had a variety of different psychiatric diagnoses. It can be argued that the results will be difficult to generalise to other settings, since diagnoses were not used as patient descriptors or markers. The irony, of course, of this kind of criticism is that these particular patients are far more representative of a clinical population of psychiatric patients than are most patients in studies of specific pure diagnostic conditions. The group was also homogeneous in that they all shared the following characteristics: for over a year, they had had symptoms of either depression or anxiety (or both) continuously, which had not responded to psychiatric out-patient treatment, including antidepressants; they had found it difficult to engage in, or respond to, other kinds of treatment; in their private lives they had a great many interpersonal problems and difficulties; the majority were not working and over 60% were drawing invalidity benefit (now termed incapacity benefit) on account of their psychiatric distress.

Clinically relevant research paradigm

A clinically relevant research paradigm is required which would facilitate rapid transmission of results from research into clinical practice. Psychotherapies need to be developed and tested on the kinds of patients who in clinical practice will actually receive them. If studies include patients who are more clinically representative than those included in past studies, treatment manuals will have to change, and 'trial therapies' will become more relevant to practising clinicians. Treatment manuals will need to address important generic therapeutic concerns such as 'engaging ambivalent clients in therapy', 'maintaining threatened therapeutic alliances', 'preventing drop-outs', 'dealing with abuse' and 'maintaining a focus in the presence of multi-symptom complaints'.

Efficacy and effectiveness

The differences between efficacy and effectiveness need to be broken down, with greater emphasis on maintaining the balance between internal and external validity, rather than an 'either/or' situation. Finally, there needs to be a clinically informed debate as to which problem groups or patient characteristics are most relevant to clinical practice, so that research efforts can be targeted appropriately.

Table 1 Total direct treatment costs for three periods of the study: baseline (3 months prior to entry), 8 weeks' trial, and 6 months' follow-up

Costs		Psychotherapy plus treatment as usual		Treatment as usual			
	Assessment period	Geometric mean (£)	*n*	Geometric mean (£)	*n*	*P*-value	Ratio of geometric means (95% CI)
Total direct treatment costs	Baseline	474	55	495	55	0.78	1.04 (0.77–1.42)
	Trial	418	52	338	51	0.29	0.81 (0.54–1.20)
	Follow-up	583	52	901	49	0.045	1.55 (1.01–2.38)

Adapted from Guthrie *et al* (1999).

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CLINICAL IMPLICATIONS

- Outcome studies should include patients who are representative of clinical populations.
- Studies in which patients have been recruited by advertisement or in a non-consecutive fashion are unlikely to have clinically representative samples.
- More studies are required which include patients with chronic neurotic symptoms or patients who are resistant to conventional psychiatric treatment.

LIMITATIONS

- The paper does not involve a systematic review.
- The paper focuses on psychotherapies with an interpersonal orientation.
- The paper is a narrative review with examples drawn from the literature.

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