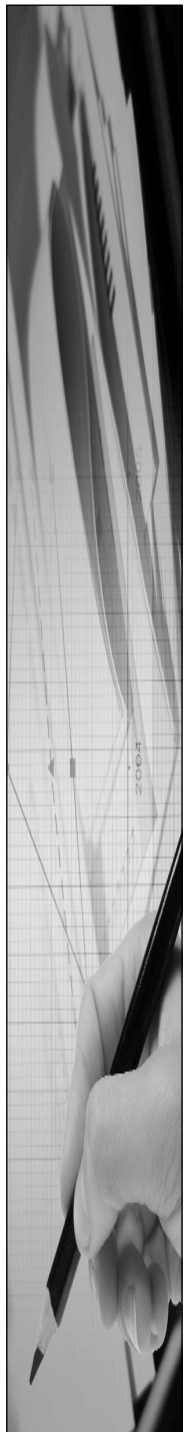


**Bill Andrews** describes the practice-based evidence that has emerged from studies of the human givens approach to date and explains why the future looks positive.

# Human givens: the evidence so far

**H**OW cost-effective is counselling? What proportion of people referred to counselling services for mental health problems get well enough to continue a normal life afterwards? This is the primary consideration for mental health commissioners who pay out for counselling services, yet it is very difficult for them to arrive at a realistic answer.



Patients may be referred by their GPs for counselling yet not actually turn up for the assessment session, which could be set for some months later. For those patients who do attend the assessment, there may be months to wait between assessment and first appointment, so, during this period too, many may fall by the wayside. Whatever proportion make it through to starting treatment, a number will attend just one session, with no one the wiser as to whether the individuals 'recovered' or just gave up. All this results in a waste of the counsellors' time – and, of course, unnecessary cost.

It is a minority who see therapy through to an agreed planned ending. If they have been attending services that measure outcomes (which most statutory services now do), they will, by the time they finish, have completed two standard measurement forms, showing the improvement (or deterioration) in their state of mental health between the first session and the last. The forms will also denote whether a patient's current state of mental health is equivalent to that of someone in the 'non-clinical' population – ie they are capable of normal day-to-day functioning. As only a small proportion of patients may arrive at this end point after referral, it is extremely difficult for commissioners to judge where they will obtain best value for money. Data gathered through the Human Givens Institute Practice Research Network (HGIPRN) reveal a very different and far more accurate story.

The Human Givens Institute is running an ongoing national study, which is gathering real-life, practice-based information about clinical outcomes in a variety of settings. Research carried out at a GP practice in Luton (see page 14) served as a pilot project. Over its 12-month period every single patient who was referred was seen and assessed and, at every session during that period, the participating human givens therapists had their clients fill in a standard form about their current state of psychological health. Ninety per cent of the patients had at least two valid outcome measures, making it possible to demonstrate whether improvement had occurred from the first session to the subsequent

session. Of the patients who started therapy and whose outcome-measure scores at the outset of treatment were below the level deemed to signify mental health, 69 per cent were improved and/or fully recovered, by the end of treatment. Forty-nine per cent were in the 'fully recovered' category. Twenty per cent were in the 'improved' category, meaning significant gains were made in treatment but the patients were still below the level signifying mental health.

What the HGIPRN is demonstrating is practice-based evidence<sup>1</sup> – the regular systematic gathering of good quality data from routine practice, which makes it possible to investigate what works. If we had no other argument than this one, mental health service commissioners should surely see that they can get a good return on their money if people see human givens therapists. However, it has been evidence-based practice that has carried most weight with the National Institute for Health and Clinical Excellence (NICE), the body responsible for providing national guidance on promoting good health and preventing and treating illness. It recommends best treatments for a whole range of conditions on the grounds of 'evidence', most notably in the form of randomised controlled trials (RCTs).

Unfortunately, while evidence-based practice is increasingly becoming mandatory in many organisations, the evidence of its efficacy is lacking in real-world terms. In the field of psychological health, the evidence for how well evidence-based treatments generalise to wider populations of service users and practitioners is sparse – and that includes evidence indicating that it isn't especially good.<sup>2</sup> It also does not take into account other variables, such as co-morbidity, differing patient populations and differential effectiveness of therapists.

Practice-based evidence, despite showing what works in the actual workplace, is also not without its critics. Steve Pilling, co-director of the National Collaborating Centre for Mental Health, one of seven collaborating centres funded by NICE to produce clinical guidelines, has not to date been impressed with practice-based evidence because most, he says, is not high quality. However, the evidence gathered through HGIPRN is high quality. We track clients throughout their therapy (ie at every single session) and we include their data even if they drop out of therapy. In our ongoing main study, where we gather data using CORE Net, a cutting-edge, internet-based tracking system from CORE IMS (Clinical Outcomes in Routine Evaluation – Information Management

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- 2 See for instance Farhall, J, Freeman, N C, Shawyer, F and Trauer, T (2009). *An effectiveness trial of cognitive-behaviour therapy in a representative sample of outpatients with psychosis*. British Journal of Clinical Psychology, 48, 1, 47–62; King, M et al (2002). *Effectiveness of teaching general practitioners skills in brief cognitive behaviour therapy to treat patients with depression: randomised controlled trial*. British Medical Journal, 324, 947–50.
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- 4 The NHS Service Delivery and Organisation R&D Programme commissioned an independent research evaluation of two IAPT demonstration sites, in Doncaster and Newham, due to report in 2009. The study was carried out by Glenys Parry, Michael Barkham, John Brazier and Gillian Hardy, Jo Rick and Kim Dent-Brown at the University of Sheffield; Tony Kendrick, at the University of Southampton; and Karina Lovell and Pete Bower at the University of Manchester. The study tests one central hypothesis: access to primary care CBT psychological therapies via newly configured service delivery models will be cost-effective when compared with existing organisation of services drawn from comparator sites.

Systems), the recovery and improvement figure is 71 per cent. The data are based on results from over 70 therapists. Up-to-date data on over 1,300 closed cases show that, where more than one valid measure is available, 51 per cent of patients are demonstrating recovery.

At the outset of this project I hoped to be able to make valid comparisons between HGIPRN data and that held within the CORE National Research Database. However, the sessional data being gathered through the HGIPRN do not allow fair comparison with the more traditional national research data, as these measure a client's state of mental health only at the start and end of therapy. This means little is known about the journey through treatment, and missing data on those who choose to terminate early compromise the quality of the data. This is one of the most common criticisms of practice-based evidence data based on measurement only at the beginning and

end of therapy. In fact, to date, it is proving difficult to find any other services in the UK using a similar 'every session' methodology, where we can make a fair comparison with HGIPRN outcomes.

All this is changing, however, to our advantage. Findings from the first 12 months' data collection from the government's Improving Access to Psychological Therapies (IAPT) initiative, gathered at its pilot site in Doncaster, have now been published.<sup>3</sup> This prospective cohort study represents a good example of the sort of robust 'real-world' effectiveness evaluation that we have been advocating in HGIPRN.

The IAPT programme has one principal aim: to support primary care trusts in implementing NICE guidelines for people suffering from depression and anxiety disorders. Most of the therapy offered under the umbrella of this programme is cognitive-behavioural therapy (CBT), although not exclusively. This major government initiative

## Results of the Luton project

MANY aspects of the human givens approach seem well suited to use in NHS general practice. I was very keen, therefore, when offered the chance to run a 12-month project in my practice in Luton, Bedfordshire, to trial its effectiveness. (Ours is a research practice which has been funded by the Department of Health for the last 10 years.) During the project period, three trained human givens therapists were based in our practice, each seeing four patients a week for a one-hour session. Any patient who would normally have been referred by our doctors and nurses to counselling provided by Luton Primary Care Trust (PCT) was referred to one of the human givens therapists instead. (The PCT's talking therapies programme covers a variety of approaches but not, as yet, human givens.)

The patients we referred were experiencing the full range of problems encountered in primary care, such as depression, anxiety, insomnia and panic attacks or physical symptoms with no organic cause, often secondary to life events such as bereavement, redundancy or relationship problems. In all, 112 patients received therapy during the project. For over three quarters, problems had persisted for more than six months and 58 per cent were taking drugs for anxiety and/or depression. Some had already had other counselling, through the PCT scheme, or had been seen by the mental health team but had not felt sufficiently helped. The project offered a great opportunity to provide them with something new, when traditional approaches had not worked for them.

So that their progress could be tracked, at each visit patients were required to complete CORE questionnaires – the full 34-question version at first and last session and a 10-question version at each session in between. This established scientific

measure, which gives scores for wellbeing, problems/symptoms, life functioning and risk, is widely used within the NHS at the beginning and end of therapy. However, the introduction of the 10-question version at each session was new to this trial and enabled therapists to use the results to inform their practice. Results were all entered on the CORE-NET national database.

Overall, 69 per cent of clients were defined as recovered or reliably improved according to their CORE scores, in an average of four one-hour sessions. This compares extremely favourably with national benchmarks because the latter do not include people who drop out of treatment whereas, in our research, there was complete data capture.

The therapy was very popular with the patients, with many finding relief from longstanding problems. Particularly striking to us was the fact that, whereas previously patients tended to come back after their six allotted counselling sessions and ask who they should see next, after human givens therapy they felt equipped with what they needed to do in order to face future difficulties without sinking into depression or becoming victim to extreme anxiety.

This is the first time that human givens therapy has been tested in a primary care setting, and doctors and nurses at our practice were uniformly positive in their evaluations of the service. Indeed, as a result, some are undergoing the human givens training themselves. We are hoping that funders within the NHS will realise that providing just four hours of human givens therapy to patients with mental health problems can provide immediate benefits – and also probably prevent them from developing more severe and enduring problems. ●

**Gina Johnson, GP**

is in the process of evaluation across the UK, where use of 'every session' outcome measures is being employed to establish if, indeed, the evidence-based treatments recommended by NICE are being effectively delivered and resulting in the expected reduction of psychological distress. Our results compare very favourably with the first findings. By the time this article appears in print, the first *independent* review of the Doncaster data, along with that from the other IAPT pilot site, Newham, should also have been published.<sup>4</sup>

### A new benchmark

It has been mandatory in this initiative that outcome measures are collected at every session. The therapy effectiveness figures collected from IAPT will, therefore, set a benchmark for what can be achieved within primary care. (It may well be that we have matched it already.) Amongst the outcome measures used within IAPT are the PHQ-9 (for depressive symptoms) and the GAD-7 (for anxiety) – the numbers referring to the number of questions in each. The CORE outcome measure has a very high correlation with both of these measures. However, it has recently become possible for organisations and services collecting data through HGIPRN (see [www.hgiprn.org](http://www.hgiprn.org)) to choose to use these measures instead of CORE, which will bring them even more closely into line with IAPT service practice and ease extrapolation from overall results.

Academics researching practice-based evidence are privately becoming convinced that, with the advent of IAPT and its evidence on outcome data collection, there will be an increasing shift away from reliance on randomised controlled trials (RCTs) as the gold standard for psychotherapy treatments – and a move towards high-quality practice-based evidence instead.<sup>5</sup> HGIPRN will quite clearly be at the forefront of this and it makes sense for all human givens therapists who are not yet measuring data to start joining in. Not only is outcome-informed practice mandatory for IAPT services, it is also a National Occupational Standard and looks set to become a government requirement. Again, we are leading the way, as learning how to use, and then to start using, outcome measures is an integral requirement of the MA programme in human givens psychotherapy, run in conjunction with Nottingham Trent University. Training in how to incorporate outcome measures into therapeutic practice, whether as a private practitioner or within a public service, is now also offered by MindFields College in a stand-alone workshop.

As we know, the therapeutic approach that has amassed most of the 'right' kind of evidence (RCTs), thus leading to its recommendation by NICE for most psychological conditions, is CBT. Yet one of its leading proponents, Paul Salkovskis, pointed

out, several years ago, the dangers of going too far down the RCT route as a means of judging effectiveness. In a paper in *Behavioural and Cognitive Psychotherapy*, which he edited at that time, he wrote, "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. ... 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."<sup>6</sup>

We are making the case that the human givens approach also comprises "a set of empirically grounded clinical interventions". Although there have been no RCTs of it as a therapeutic approach, most of its individual elements *have* been validated through clinical trials. Indeed, almost all the research evidence cited in the newly updated NICE guidelines for depression concern techniques that are routinely used in human givens therapy.<sup>7</sup> Clinical psychologist and human givens therapist Shona Adams and her psychology assistant Becci Roberts are currently mapping elements of human givens (eg cognitive-behavioural approaches, guided imagery, reframing, etc) to the evidence-based findings already recognised by NICE for each of these interventions. This should establish the empirical basis of the human givens techniques, while acknowledging the difference in the underlying organising ideas.

In an earlier paper, Salkovskis described what he called the hourglass model of psychological therapies research (see below).<sup>8</sup> This shows how clinical observation, exploratory research, theory development, other forms of research, uncontrolled trials and case studies must all be executed before it is appropriate to carry out an RCT to consolidate findings gleaned up to that point. As can be seen from the illustration, much must precede the RCT and much must follow it, when a method that is found to be effective is put to further test in real-world settings. By showing

that the human givens approach uses empirically validated methods, we should be able to flow through the RCT area of the hourglass, straight on to effectiveness. The question then becomes, "Does the package that makes up the human givens approach work in real-life settings?" The sooner every therapist using this approach undertakes to gather outcome evidence, the sooner we will be able to demonstrate a resounding "Yes!" ■

#### The hourglass model of psychological therapies research

Clinical observation;  
exploratory research;  
theory development;  
experimental + research +  
controlled trials + case series

Randomized controlled trial

Service models research

Real-world research



To learn how to get started and to get up-to-date results, visit [www.hgiprn.org](http://www.hgiprn.org). For details of the MindFields workshop, 'Incorporating outcome measures into your practice', visit [www.mindfields.org.uk](http://www.mindfields.org.uk)



**Bill Andrews** is a senior associate with the International Centre for Clinical Excellence, a new worldwide initiative designed to explore empirical findings around excellence in the delivery of behavioural health ([www.groupnos.com](http://www.groupnos.com)). As well as providing independent consultancy and supervision in outcome-informed practice, he is a trainer with MindFields College and teaches on the MA programme in human givens psychotherapy at Nottingham Trent University. Bill has a part-time private human givens therapy practice in Sheffield.

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