

Evaluation of the effectiveness of Human Givens (HG) therapy using a Practice Research Network

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Summary

The proposal is for a multi-site study to evaluate the effectiveness of therapists trained in the Human Givens (HG) approach in treating clients with mental health problems (appendix I). We will examine whether therapists demonstrate equivalent and consistent outcomes regardless of either the severity of client distress at intake, location of service setting or type of service. We will compare HG therapist outcomes with national benchmarks established by CORE IMS (appendix II). We will also examine the sustainability of clients' improvement 3 months after completion of treatment.

Introduction

According to the Layard report (Layard, 2004), 13% of men and 19% of women in the UK are suffering from mental disorder. 91% of clients of working age consulting their general practitioner will be treated in primary care. However mental health services in the NHS have historically suffered from lack of investment, and few primary care professionals have had training in this area. As a result, there is poor access to treatment for the majority of clients who suffer from depression and anxiety disorders, which make up the bulk of clients. The failure to provide access to treatment is reflected in the ever rising numbers of mentally ill people on incapacity benefit. Layard's suggestion is to look to evidence based treatments to provide the solution. He believes that there is a need to train some 10,000 extra therapists giving evidence-based psychological treatments. He sees many of these therapists being trained by a 2 year part-time diploma while continuing to work at their existing employment. While much of this

might be done within the NHS, he recognises the role for the private sector in the delivery of service and he suggests that this avenue should be explored as an additional means of increasing access through commissioning. He writes that it is not important whether services are publicly or privately supplied, so long as there is good control of quality and cost. He suggests that these significant numbers of therapists required will be trained in cognitive behavioural therapy, systemic family therapy, psychosocial interventions and “other dynamic therapies”.

In Sept. 2006 Prof. Liz Bondi (Bondi, 2006) published a report for COSCA in which she stated “Although some studies point to modest variations in the effectiveness of different approaches for different conditions, the overwhelming message from these studies is that orientation is not a significant factor in relation to effectiveness.” This position is supported by findings from the CORE National Research Database (Stiles, Barkham, Twigg, Mellor-Clark, & Cooper, 2006).

The Department of Health (DH) published a report investigating the organization and delivery of psychological services in July 2004 (DH, 2004). In considering effectiveness of therapy it is written in the report that “.....while attempts have been made to establish empirically validated treatments.....in general brand names rarely predict outcomes and in direct comparisons most studies show a broad equivalence between therapies.....” The report goes on to suggest a recommendation of “.... incorporating measures of outcome into your psychological therapies service as a matter of routine.”

Prof. Glenys Parry, Prof. of Applied Psychological Therapies at Sheffield, suggests that practice based research is vital, and advocates the development of Practice Research Networks, where members agree to pool data relating to clinical outcomes, using the same set of measures, in order to enable analysis of regional or national datasets. She writes, “By developing high quality clinical databases on large clinically representative samples, Practice Research Networks can contribute an important source of evidence on the effectiveness of services as delivered, and encourage a research approach to the evaluation of outcome” (Parry, 2000).

The aim of this study is therefore to use a Practice Research Network to evaluate whether therapists trained in the HG approach are effective with their clients out in the real world of everyday practice. This will inform the debate on whether the HG approach could be one method that meets the Layard suggestion of “other dynamic therapies,” and will enable an assessment of the implications for training or re-training of therapists in terms of cost benefit.

Setting

Currently HG Therapists use outcome measures routinely in their work in a wide range of different settings up and down the UK. Some therapists are in private practice. Some work within the NHS. Others work in the voluntary sector, on rehabilitation projects, for charities etc. The multisite study will involve 30 therapists working in a mix of these settings with a variety of funding sources. They will be linked by a Practice Research Network, with training and IT support arranged by a central co-ordinator. This should ensure consistency of data entry.

Participants

A minimum of 300 adult clients who are working with Human Givens therapists in a range of settings in England, e.g. NHS general practice, private practice, University counselling services, EAP schemes, Personal Injury work, voluntary sector etc.

Methods

HG therapists joining the study will agree to offer outcome measures routinely in an agreed consistent format to every client seen during the test period. Clients will be informed of the process (Appendix III). They will either record this anonymous data electronically using the internet based CORE Net system or submit paper versions to the administrator for subsequent entry onto CORE Net.

The CORE Net system is a computerized, internet-based evaluation support system for the CORE Therapist Assessment Forms, Outcome Measures and End of Therapy Forms, with the potential flexibility to include data from other measures. Therapists can decide whether to present the measures to clients as paper measures that they then fill in after the session, or, when possible, directly onto the computer interface. The anonymized data will be collated by a central administrator. From the commencing date of the study participating therapists will offer outcome measures to all clients they see in the trial period. It is anticipated that each therapist will provide data for a minimum of 10 clients in the trial period. Wherever possible, clients will be offered an outcome measure at every session, at 1 month, and 3 month follow-up (appendix II)

In order to ensure that participants provide CORE data that is representative of their normal caseload we will ensure that methods are used to secure a concurrent series of clients.

Instruments

CORE Net—choice of CORE Therapist assessment form, CORE end of therapy form, CORE 34, 10, ORS/SRS and IES-E (A thorough description of all measures used in the study is contained in Appendix II).

Ethics

It is not anticipated that ethical clearance will be required for this study as it utilizes a methodology for naturalistic outcomes audit in-line with recommendations for routine measurement as advocated by the DH (DH, 2004). Informed consent will be sought for all participating clients (see Appendix III). For NHS patients, permission will be sought from the local PCTs as required.

Hypotheses

1. Human Givens practitioners see a case mix that is similar to NHS primary care patients presenting with common mental health difficulties.
2. Human Givens Practitioners achieve rates of recovery and/or improvement similar to published figures for primary care populations.

Standardized, recognized statistical techniques utilized by the publishers of each of the measures will be used to test each of the above hypotheses.

Dissemination

The results of this research will be submitted for publication in a peer-reviewed journal and presented at national conferences e.g. PRIMHE.

Timeline

Months 1-3: preliminary work, familiarization with CORE Net system, and development of training materials for participant therapists in the use of CORENET and ORS/SRS.

Months 4-9: Data collection period.

Months 10-14: Completion of client 1 month and 3 month follow up, analysis of data and preparation for publishing.

Costing

CORE Net user licence x 30@£150.00	£2,000.
Specialist CORE advice on training, analysis, interpretation and benchmarking from CORE IMS Ltd 2 days @£600. per day	£1,200.
Research advisor and statistician £25.00 an hour. Est.100 hours	£2,500.

Researchers' time, including therapist training, travel, subsistence, preparation of on-line training, preparation for publication, misc. ongoing costs.	£20,000.
Therapist travel to training and conferences costs, subsistence, room hire, misc.	£6000.
Postage, Paper etc.	£500.
Administration staff, data entry, misc. est. @ 1 hour per client 375 hours @ £8.00 an hour	£ 3,000.
Total	<hr/> £35,200.

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Appendix I

Human Givens Approach

An integrated bio/psycho/social approach to the training of psychotherapists, derived from Human Givens (HG) psychology has been developed by Griffin and Tyrrell (Griffin & Tyrrell, 1997) [Griffin & Tyrrell, 2003]. This integrates evidence based tools from other therapies (Roth & Fonagy, 1996) and draws upon up to date scientific insights into the psychology and biology of human functioning (LeDoux, 1998) [Hull, 2002]. It has a peer reviewed quarterly journal, *Human Givens*, with a distinguished editorial advisory board.

Training in the Human Givens approach has attracted interest from a wide range of people since its inception in 2000. Many people already trained as psychologists, social workers and therapists from varieties of orientations have taken the training and feel it has greatly enhanced their work. Others with no direct training in counselling or therapy have also trained as HG therapists and are successfully working with clients. Training is delivered in stages. Part 1 involves attendance at 16 days of workshops and seminars, currently held at various venues around the country as well as in-house provision of training for services. Part 2 involves attendance at a 2 week intensive training programme. Part 3 involves submission of videotape examples of therapists working with clients. Qualified therapists adhere to the code of ethical practice, continuing professional development, and supervision requirements laid down by the Human Givens Institute. The model of training fits very well with the proposed model suggest in the Layard report and can be accomplished comfortably in a 2 year period on a part-time basis.

While, as yet, the organization does not have a published evidence base, several HG approach therapists have been contributing data from practice since July 2005, using Outcome rating Scale (ORS) measures for evaluation of effectiveness. The results on completed cases suggest clinical and reliable change with around 74% of clients in an average of less than four treatment sessions (see attached chart). This speed of response makes HG a very cost-effective form of therapy.

Appendix I contd.

Human Givens

The term 'human givens' refers to our fundamental physical and emotional needs and the innate resources to help us fulfill them. These have evolved over millions of years and are our common biological inheritance, whatever our cultural background and it is because these needs and resources are incorporated into our biology that they are called 'givens'. All humans are driven by nature to get these needs met in the environment in order to fulfill themselves.

In psychotherapy it is the emotional needs we are mainly concerned with. They include: the need for security; the need to give and receive attention; the need for a sense of autonomy and control; the need to feel connected to others and be part of a wider community; the need to feel competent which comes from successful learning and effectively applying skills (the antidote to 'low self-esteem'); the need for privacy (to reflect on and consolidate our experiences) and the need to be 'stretched' in what we do, from which comes our sense that life is meaningful.

The resources Nature provides us with include: the ability to learn and add new knowledge to innate (instinctive) knowledge, memory and the ability to forget; curiosity, imagination and the ability to problem solve; the ability to focus attention; the ability to understand through metaphor (pattern-matching); self-awareness (an observing self); resilience; the ability to empathize and connect with others; a dreaming brain that de-arouses the autonomic nervous system every night thereby keeping us sane.

The premise is simple: those whose needs are well met in the world do not have mental health problems and are better integrated with other people. Those whose needs are not fulfilled, for whatever reason, suffer considerable distress and may develop mental illness, and/or, as a means of coping, antisocial behaviours.

Appendix II

THE MEASURES

The CORE system

CORE is an abbreviation for Clinical Outcomes for Routine Evaluation (Mellor-Clark. J, Barkham. M, Connell. J, Evans. C, 1999) It is the first standardized public domain approach to audit, evaluation and outcome measurement for managers and practitioners working in UK psychological therapy and counseling services. It provides a framework for responding to the increasing demand in health and other sectors to provide evidence of service quality and effectiveness.

CORE was designed as a **quality evaluation system** to profile and enhance psychological therapy service delivery and development. Consequently, data collation and analysis has a focus that is broader than 'outcome' and incorporates wider factors that include client context and therapy processes. These context and process factors have been allied to models of quality assurance that place health outcomes and/or clinical effectiveness in the context of factors such as service accessibility, clients' attendance efficiency, and therapy appropriateness.

Users of the CORE System

Increasingly, all providers of psychological therapy across both public and private sectors are being asked to provide evidence of their service effectiveness and overall quality.

In the National Health Service CORE is used to help risk assessment and meet clinical governance and performance management requirements.

Psychiatrists, psychotherapists, clinical psychologists, counselors and other professionals providing talking therapies across NHS primary, secondary and specialist care use CORE System tools and CORE-PC software.

Outside the NHS, workplace counseling, student counseling, palliative care, drug and alcohol services, and private practice are all sectors from which the CORE System has attracted enthusiastic supporters to the **CORE Benchmarking Network**. The main advantage of using a standardized system for monitoring and managing service delivery is that it offers the opportunity to compare your service profile with national benchmarks that provide comparative indicators and descriptors.

Appendix II contd.

Some of the benefits of the CORE System:

- Use of the UK's most widely used system for service quality monitoring, measurement and benchmarking
- CORE System forms are free to download, copy and use
- The System is easy to use and implement
- Ongoing training and CORE-PC software support is available
- CORE-PC software facilitates data storage and provides powerful data analysis and reporting
- Access to membership of the CORE Benchmarking Network for networking and sharing best practice
- Ongoing research & development ensure the system's long term relevance and utility
- The CORE System facilitates performance management and helps fulfil NHS clinical governance standards & requirements
- The new COREnet web based system is paperless and allows instant and easy transmission of data as well as providing real-time feedback to the therapist.

CORE FORMS

CORE outcome measures (OM) 34, 10. CORE therapist assessment form, CORE end of therapy form.

For samples of all CORE forms see attached documentation.

The Outcome rating Scale (ORS) and the Session Rating Scale (SRS)

The ORS and SRS were developed to track client progress and perception of the therapeutic alliance over the course of treatment. Both are known as “visual analogue” scales. On such measures, content and complexity is kept to a minimum. Clients simply place a hash mark on the line nearest to the pole that best describes or “fits” with their experience.

The scales were purposefully designed for use at each session, the ORS at the beginning, the SRS at the end, because (1) therapists are often unaware when clients are not progressing or deteriorating during treatment; (2) clients' and therapists' ratings of the alliance often have a low correlation; and (3) clients' ratings of the alliance have a higher correlation with outcome than therapists'. (Duncan, Miller, Sparks, 2004)

For samples of ORS and SRS forms see attached documentation.

Appendix II contd.

The Impact of Events, Extended Scale (IES-E)

The Impact of Events, Extended, Scale (IES-E) is a validated, psychometrically tested scale provides reliable clinical scores to help assess the level of distress due to the impact of a traumatic event or events. The scale was further developed from the original IES scale (Horowitz, Wilner & Alvarez, 1979) so that symptoms related to arousal could be satisfactorily measured (Tehrani, Cox, Cox, 2002)

For a sample of the IES-E see the attached documentation

Method of administration.

At the beginning of the first session clients will be informed about the measuring process (appendix III) and if they consent, requested to fill in a CORE OM and an ORS in that order.

At the beginning of subsequent sessions the client will be asked to fill in a CORE OM and an ORS. At the final session the client will again be requested to fill in a CORE OM and a final ORS. Near the end of each session the client will be asked to fill in an SRS, thus providing feedback on each session.

If it is clear that there is an event that is the trigger for a traumatic response, the IES-E scale may also be completed as a supplementary outcome measure. If an IES-E scale has been used the client will be asked to complete it again at the last session.

In the case of a planned ending the therapist will fill in a therapist assessment form for each client after the 1st appointment and an end of therapy form at the end of treatment. In the case of an unplanned ending, when it appears certain that the client is not returning, the therapist will also fill in an end of therapy form.

At 1 month and 3 month intervals the client will be requested, by post, to fill in a CORE OM.

Appendix III

Human Givens Institute Practice Research Network

Client Information Sheet

This Practice Research network uses a standard evaluation system (CORE) and adds additional measures (IES-E, ORS/SRS). All of these approaches have been developed to help providers of counselling and other psychological therapies to deliver and develop the best possible services to clients seeking help for their difficulties and concerns. As part of the system, all clients are asked to complete a brief questionnaire before and after their therapy sessions. These questionnaires assist us in understanding your problems, and ultimately, the degree to which we help you with those problems. We hope you will agree to complete the questionnaires, but would like to emphasise that participation is entirely voluntary and declining to complete them will not affect your access to therapy in any way.

About our evaluation:

- We would like you to complete a brief questionnaire before and after your contact with the therapy service. Your therapist may also complete simple record forms relating to your therapy
- To assist in monitoring your ongoing progress and how well the work we do together is fitting for you your therapist will also ask you to complete some very brief forms (CORE 10 & ORS/SRS) at each session, at the beginning and at the end.
- The purpose of these forms is to help us better understand more about your problems that you wish to address in counselling, to assist us directly in our work with you and also to help us learn how best to improve our services.
- The processing of completed forms is co-ordinated by the Human Givens Institute Practice Research Network research team in order to assist us further in the development of our services.
- The information from the forms will be treated as strictly confidential. **No names or personal details of any kind are used on any forms that leave your personal records.**
- Filling in the forms will be taken to represent your agreement for the anonymized data to be used for service evaluation.
- Research clearly illustrates that ongoing feedback from the client about the therapeutic relationship and how change is progressing in therapy assists in improving the outcome of therapy. However, we wish to emphasise that participation in this feedback process is entirely voluntary and should you choose to at any point decline to complete the forms your access to therapy will not be compromised.

CURRICULUM VITAE

Georgina Mary Johnson

Date of birth: 8 May 1955

Registered degrees and qualifications:

BSc (Anatomy) 1 st class honours	1976
MB BS (Guy's Hospital)	1979
MRCGP	1983
MSc in Medical Anthropology (Brunel) with distinction	2002

Other Qualifications:

JCPT certificate of vocational training	1983
Joint certificate in family planning	1983
BMAS Certificate of Competence in Acupuncture	2005

Current post:

Principal in General Practice and Research Director, Stopsley Group Practice, Luton. This practice receives research infrastructure funding from the Department of Health, and in 2004 was accredited by the Royal College of General Practitioners as an investigator-led research practice.

Clinical experience:

House Officer

- Medicine, Luton and Dunstable Hospital, 1979
- Surgery, Edgware General Hospital, 1980

Senior House Officer, Luton and Dunstable Hospital

- Medicine, 1980
- Accident and Emergency, 1981
- Obstetrics and Gynaecology, 1981
- Paediatrics, 1982

General Practice Registrar, Luton / Leighton Buzzard 1982

General Practice Principal, Dr. Adler and Partners, Luton, 1983-1993

Other positions held:

- Clinical Assistant in Paediatrics, Luton and Dunstable Hospital, 1983-1993
- Convenor, South Bedfordshire Practitioners' Group, 1983-2003
- Audit facilitator, Medical Audit Advisory Group, 1990-1995
- Guidelines Co-ordinator, Bedfordshire Audit and Education Group, 1995-9
- Woman Specialist Police Surgeon, Bedfordshire 1991-1994
- Member of Anglia and Oxford Multi-Centre Research Ethics Committee, June 1998-2000

Publications:

The Minor Illness Manual (3rd edition). Johnson G, Hill-Smith I, Ellis C. Radcliffe Publishing Ltd, Oxford 2006. ISBN 1 85775 696 7

Remedy or cure? Lay beliefs about over-the-counter medicines for coughs and colds. Johnson G, Helman C. British Journal of General Practice 2004; 54: 98-102

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1990; 40; 146-9

Infertile or childless by choice? A multipractice survey of women aged 35 and 50.
Johnson G, Roberts D, Brown R, Cox E, Evershed Z, Goutam P, Robinson R,
Sahdev A, Swan K, Sykes C. BMJ 1987 294; 804-6

CURRICULUM VITAE

William Peter Andrews

Date of birth: 20 August 1955

Registered degrees and qualifications:

BDS, NUI (CORK)	1977
HGDip.P	2004

Other training

Medical and Dental Hypnosis	1977
Clinical attachment in Periodontology, Bristol	1980 -1981
Postgraduate study of occlusion	1984
Clinical Instructor at Charles Clifford Dental School	1991-1993
Production of original training video material for postgraduates on principles of occlusion	1992

Attendance of extensive postgraduate training every year throughout 22 years in practice as a dentist

NLP (Robbins Institute)	1995 - 1996
William Glasser Institute, Ireland	2005
EFT training	2005
Trainer Certification ISTC (www.talkingcure.com)	2006
Msc in Psychological Trauma, University of Chester 2 year course, ongoing	2007-

Recent History:

Retired on grounds of ill health from dentistry in 1996. Diagnosed with bi-polar disorder, December, 1994. Extensive experience of the receipt of psychiatric services including medication over a 9 year period. Free of all medication since introduction to "human givens" in 2003.

Current posts:

- Work on a vocational basis as director of "Effective Therapy" in Sheffield (www.effectivetherapy.org)
- Steering research project on behalf of the Human Givens Foundation (www.hgfoundation.com)
- Certified Trainer with Institute for the Study of Therapeutic Change (ISTC)
- (www.talkingcure.com)
- Studying for MSc in Psychological Trauma at University of Chester

Publications:

Andrews, W (2004). *Depression: the myth of 'chemical imbalance'*. Human Givens, 11, 2, 13–19.

Andrews, W (2007). *Doing what counts*. Human Givens, 14, 1, 32–37.