Ethics and Effectiveness: Challenges in psychotherapy research and practice

or

How do we know what is good for our patients?

Dr Stephen Buller

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Introduction

- In this presentation I am going to examine some perspectives on effectiveness in psychotherapy research and practice starting from the viewpoint of ethics, and particularly professional ethics.
- My interest in ethics has several roots. For more than 25 years I have been involved in ethics committees in the NHS, in universities, and in professional organisations. During this period I was teaching ethics and managing research ethics.
- I joined the NHS in the mid 1970's from a background in medical research, pursuing a career as a clinician and researcher in psychiatry.
- It was a period when NHS psychotherapy and psychological therapy services, which had been relatively small, were starting to develop and practice can be considered as highly experimental. Nobody really knew what worked or why – although some of us thought we knew.
- Here we dreamed about a time when psychotherapy would be widely available through primary care.
- Over a period of years I trained in a range of psychological therapies, began working as a mental health specialist in psychotherapy, and eventually became lead clinical specialist and service manager for psychotherapy services in Derby City and Derbyshire.
- There was growing confidence that we were starting to identify therapies that would be routinely more effective than others.
- I now work as a clinician, researcher, academic, and in delivering strategic and organisational consultancy, across a range of statutory, non-statutory, charitable, professional, provider, and commissioning organisations.
- Additionally I maintain an involvement in professional ethics at a number of levels.

Identifying and Accessing Accounts and Narratives About Professional Ethics

- As a clinician I have listened to, and engaged with, service user and patient narrative accounts of there experiences of my work and, of the work of other professionals, services and organisations.
- In my role as an academic and educator I have listened to students talk about their experiences of engaging for the first time in clinical practice and research.
- As an academic and educator I have listened to fellow academics and educators talk about their experiences of students engaging for the first time in clinical practice and research.
- Through my involvement in strategic planning for mental health and psychotherapy services at local and UK national levels I have listened to service commissioners, service providers, researchers, clinicians and service users and patient discuss, dare I say argue, about their experiences.
- From my work with institutional and organisational research governance and research ethics committees at local and UK national levels I have participated in dialogue about the range of ethical issues and dilemmas that are faced in these arenas.
- As a member and chair of ethics committees for UK national professional organisations I have also been immersed in an array of ethical issues confronting practice and research.
- In the same way, my role as reviewer of research articles, research proposals for governance, ethics and funding bodies has led me into a forest of ethical discussion.

Ethical Discourse and Profession Life

- This presentation is from accounts of ethical discourse in professional life.
- Ethics is a branch of philosophy that can be described as systematizing, defending, and recommending concepts of moral character and conduct. Ethics is concerned with finding good, and separating it from bad – right from wrong.
- Within the general field of ethics we find some distinctive approaches to these descriptions of character and conduct which include:
  - Consequentialism - refers to an ethic which privileges the consequences of an action as criteria for a judgement abut the value of the action – 'the end justifies the means'.
  - Hedonism – based on an assumption that ethical action is aimed at maximising pleasure and minimising pain.
  - Deontology – relies on separating conduct from character, intention and consequence, and imputing a value, good or bad, to the conduct itself.
  - Pragmatic ethics – proposes that 'good' evolves over time in social reform and social development
  - Postmodern ethics – suggests that, from a relativist and social constructionist position, each individual, in every moment and situation, is obligated to make a unique ethical decision.
  - Virtue ethics – is perhaps the oldest tradition within ethics, and it can be argued has had the greatest impact on our current understanding of professional ethics and codes of ethics.
- The last of these, virtue ethics, has become a dominant feature of professional ethics.

Virtue Ethics

- Virtue ethics is perhaps the most influential approach to ethics in professional contexts, and is also arguably the oldest.

  Virtue ethics' founding fathers are Plato and, more particularly Aristotle (its roots in Chinese philosophy are even more ancient) and it persisted as the dominant approach in Western moral philosophy until at least the Enlightenment. It suffered a momentary eclipse during the nineteenth century but re-emerged to dominance in the late 1950's.
  (Rosalind Hursthouse 2013)

  This theory [virtue ethics] emphasizes the moral character of human beings. According to Aristotle, a moral individual is one who strives for excellence and virtuous living. An individual becomes a moral person according to how he lives his life in practice, that is, according to his virtues. Someone who acts decently becomes a decent individual, and someone who acts bravely turns into a brave man.
  (Ruth Landau and Gaby Shefler 2011 p9)

- Virtue ethics relies on an understanding of a virtuous person who acts, or conducts themselves, with characteristics such as integrity, beneficence, benevolence, compassion, caring, decency and bravery.

- So ‘doing good’ is the conduct of a virtuous person acting with integrity.

Hippocrates and Virtue Ethics

- In a Hippocratic tradition, rooted in a context of virtue ethics, beneficence is contrasted with maleficence, and the call to *"first do no harm"*.

  Also I will, according to my ability and judgment, prescribe a regimen for the health of the sick; but I will utterly reject harm and mischief
  (Hippocratic Oath circa 480BC)

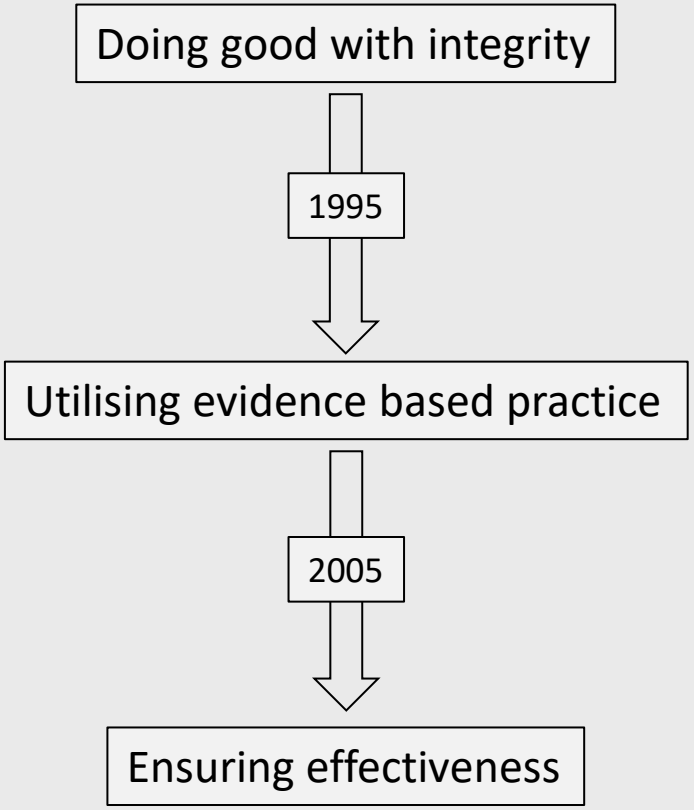
  Practice two things in your dealings with disease: either help or do not harm the patient
  (The Hippocratic Epidemics, Book 1 circa 450BC)

  First do no harm
  (Credited to Thomas Inman 1860)

- So non-maleficence is added to the list of characteristics of the conduct of a virtuous person already outlined – integrity, beneficence, benevolence, compassion, caring, decency and bravery. So 'doing good' and 'avoiding harm' is the conduct of a virtuous person acting with integrity.

Good (Virtuous) People Do Good Jobs

Development of Professional Ethics and Codes in Psychotherapy



Go Go

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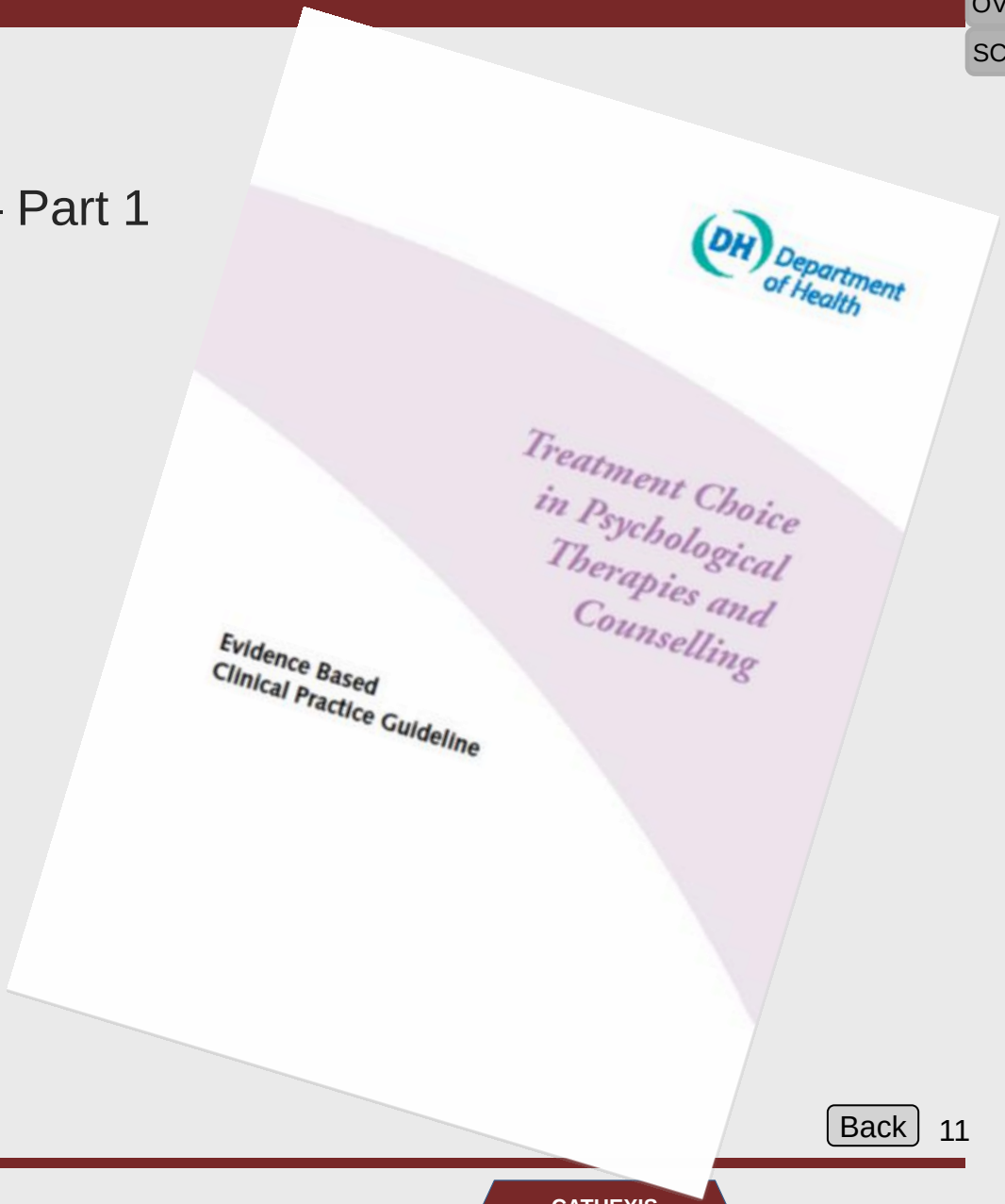
Evidence Based Practice – Part 1

(2001)



Evidence Based Practice – Part 2

The ‘five step model’ for evidence based practice (Sicily statement 2003/2005/2009):

- Translation of uncertainty into an answerable question.
- Systematic retrieval of best evidence available.
- Critical appraisal of evidence for validity, clinical relevance and applicability.
- Application of results in practice.
- Evaluation of performance (routine use of clinical outcome measures).

How do we know we are doing good and being effective?

Examining Peer Reviewed Published Research

When we consider peer reviewed, published research there are a number of issues:

- ❑ Cohort studies and case series clinical trials - effectiveness Go
- ❑ Randomised controlled trials – effectiveness and efficacy Go
- ❑ Replication – as validation of study and trial results Go
- ❑ Meta-analyses – a substitute or 'work around' for replication Go
- ❑ Systematic reviews – a critical synthesis of studies and trials Go

These are all issues of an empirical, experimental model which embrace progression from very small scale toxicity studies, through case series and cohort studies for effectiveness, to randomised controlled trials for efficacy and replication. Fundamental in this progression are a rigorous applications of standards and quality assurance which are ultimately are essential in replication in research, and replication in effectiveness in practice. Hence we arrive at a hierarchy of evidence.

This is an ethical issue in 'doing good with integrity' and achieving 'effectiveness'

Scoring for Reliable and Reputable Research Studies

Research Scorecard V4.01	Scorer name/ID: Completion date:
Scored research reference:	

Carefully read the research report/article and then score according to accompanying instructions.
(Use a √ or X to indicate your answer)

Part 1: Clinical Trials and Randomised Controlled Trials	Not at all	A little bit	Moderately	Quite a bit	Fully
1. Is there clear and adequate description of patients participating in treatment in the study, including details of diagnosis, severity and complexity?					
2. Is there clear and adequate description of treatments delivered in the study, including detailed treatment protocols and treatment manuals? (include evaluation of controls/TAU)					
3. Is there clear and adequate description of therapists delivering treatment in the study, including training and competence?					
4. Is there clear and adequate description of measurements and assurance of therapist adherence to treatment protocols and manuals?					
5. Is there clear and adequate description of research method and data analysis?					
6. Is there clear and adequate description of outcome measures used in the study and their credibility?					
7. Is there clear and adequate description of results, including treatment effect sizes (variance) and the treatment success rates (Jacobson-Truax and percentage change)?					
Part 2: Randomised Controlled Trials only	**Not at all**	**A little bit**	**Moderately**	**Quite a bit**	**Fully**
8. Are there independent effectiveness studies (case series clinical trials) for main treatment(s) in the RCT?					
9. Are there independent effectiveness studies (case series clinical trials) for control treatment(s) in the RCT?					
10. Is there clear and adequate description of control treatment(s) delivered in the study, including TAU, with detailed treatment protocols and treatment manuals?					
11. Are controlled treatments, including TAU, real competitors for use with the target patient population?					

For office use
Score part 1: **Score part 2** **Total score:**

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Scoring for Reliable and Reputable Research Studies – Part 1

A reputable and reliable research study, which informs evidence based practice, and points to an empirically supported and effective treatment, requires a clear and adequate description of:

1. patients who participate in treatment in the study. This includes details of diagnosis, severity and complexity.
2. treatment delivered in the study. This means detailed treatment protocols and treatment manuals.
3. therapists delivering the treatment in the study, including their training and competence.
4. measurements and assurance of therapist adherence to treatment protocols and manuals.
5. research method and data analysis.
6. outcome measures used in the study and their credibility.
7. treatment effect size (variance statistics) and the treatment success rate (Jacobson-Truax or percentage improvement).

These factors ensure that a research study, and treatment being studied, can be reliably replicated.

Scoring for Reliable and Reputable Research Studies – Part 2

For randomised controlled trials we additionally ask:

1. Are there independent effectiveness studies (case series clinical trials) for main treatment(s) in the RCT?

2. Are there independent effectiveness studies (case series clinical trials) for control treatment(s) in the RCT?

3. Is there clear and adequate description of control treatment(s) delivered in the study, including TAU, with detailed treatment protocols and treatment manuals?

4. Are controlled treatments, including TAU, real competitors for use with the target patient population?

An RCT has significant weakness if the control is not a real competitor for the most effective treatment. Treatment as usual (TAU) is often a misleading control and the study would be better framed as a case series, pre-post evaluation, study where effect size and RCI are a more important focus for the analysis and discussion. Small effect sizes in an RCT where TAU is the main or only control can lead to misleading conclusions.

All of these factors ensure that a research study, and treatment being studied, can be reliably replicated.

Replication

- Replication is a standard and essential component of an empirical, experimental method.
- Replication is designed to validate a research method and its application in a way that the results of a research study can be assumed to be reliable, or variability can be identified.
- This is not the same as repeated measurement.
- An experiment is conducted and the method is written as accurately as possible. The experiment is then repeated using the written method as a guide. Ideally the experiment is repeated by a different researcher or research team, following the original researcher's written method.
- It is important that the written method is detailed and specific so that repetition is possible. Hence the development of scoring systems reliable and reputable published studies.
- An accurate, detailed and specific written method iis also required so that effectiveness identified in research can be replicated by practitioners in clinical practice.

Meta-analyses

- A meta-analysis can be regarded as substitute or ‘work around’ for an absence of replication in empirical and experimental processes.
- Standards for meta-analyses have been developed to address a concern about ‘garbage-in-garbage-out’ (GIGO).
- The selection of studies to be subjected to meta-analysis is required to be rigorous and detailed.
- Only high quality studies of which can be shown to be reliable and reputable should be selected.
- Studies selected are required to be ‘homogenous’ on factors important in replication, and which make studies reliable and reputable.
- The more ‘heterogeneous’ the studies included the less reliable the meta-analysis.

Ethics and Effectiveness – 'The Game Show'

We asked 28 experts:

	Cohort/Case Series Trials	Replication	Randomised Controlled Trial	Replication	Meta-analysis
Cognitive Behaviour Therapy (CBT)	?	?	?	?	?
Cognitive Therapy (CT)	✓	✓	✓	✓	✓
Couples Therapy	?	0	0	0	0
Dialectical Behaviour Therapy (DBT)	✓	✓	✓	✓	✓
Dynamic Interpersonal Therapy (DIT)	0	0	0	0	0
Emotion Focused Therapy (EFT)	?	0	?	0	0
Interpersonal Therapy (IP)	✓	?	✓	?	?
Psychodynamic Psychotherapy (PP)	✓	0	✓	0	0
Short-Term Dynamic Psychotherapy (STPP)	✓	0	✓	0	?
Systemic Family Therapy	?	0	0	0	0

✓ = yes
? = questionable
0 = no

Cognitive Therapy as an Example of Effectiveness

- Cognitive therapy has high quality case series/cohort studies, RCTs, and replication.
- Research has shown that typical treatment effectiveness is 50% recovery. That is NNT=2 (two people treated, one [50%] recovered).
- This is important because it reflects achieved recovery rates in the use of approved antidepressants (50% and NNT=2), which is the gold standard for research in these forms of psychotropic medication.
- In other words cognitive therapy can be considered to have equivalent or comparable outcomes to antidepressant medication in the treatment of mild to moderate depression.
- Additionally cognitive therapy, along with a small number of other treatments from within the cognitive-behavioural cluster, has been shown in research studies to have a significant impact in the treatment of mild to moderate anxiety disorders.
- Cognitive therapy has become an important and central treatment in the IAPT development. However it is important to recognise the corollary, that 50% of those treated will remain dysfunctional and symptomatic, and continue to need help or assistance.
- What happens to this latter group of people? IAPT services have adopted a range of other options of psychological therapies, including Interpersonal Therapy (IPT), Dynamic Interpersonal Therapy (DIT), and Short-Term Psychodynamic Psychotherapy (STPP), which all have less than optimal but important evidence for effectiveness with mild to moderate disorders. Additionally some patients, perhaps as much as 20%, are ‘stepped-up’ to secondary and tertiary services.

Relative Effectiveness of Other Therapies

- When we turn to other forms of therapy there is a significantly different picture.
- Dialectical behaviour therapy (DBT), part of the cognitive-behavioural cluster, appears to have effectiveness in the treatment of very severe self-harm amongst a specific sub-population of personality disorder (34% recovery, NNT=3).
- Similarly transference focused psychotherapy (TFP), part of the psychodynamic cluster, appears to have effectiveness in the treatment of a sub-set of complex personality disorders.
- Evidence appears to be accumulating for the effectiveness of other treatments such as mindfulness-based cognitive therapy (MBCT) (28% recovery, NNT=4) and short-term psychodynamic psychotherapy (STPP) (35% recovery, NNT=3).
- Long-term psychodynamic psychotherapy (LTPP) also appears to hold claim to effectiveness in particular conditions (15% recovery, NNT=7).
- Research studies appear to demonstrate these important forms of psychotherapy and psychological therapies can achieve between 15% (NNT=7) and 35% (NNT=3) recovery in particular conditions.
- When we consider research in other forms of mental health treatment with severe and complex disorders, such as pharmacological research into psychotropic medications, then we find similar levels of possible effectiveness - recovery between 15% (NNT=7) and 30% (NNT=4).
- In our current state of knowledge and experience we do not have an abundance of outstandingly effective treatments. We find no treatments to match the level of effectiveness of cognitive therapy in the treatment of mild to moderate depression.

Effectiveness in a Wider Healthcare Context

- In a wider healthcare context we can look at comparative outcomes between physical health and mental health.
- What is probably not commonly understood is how much of healthcare activity is directed towards diseases, conditions and disorders which do not recover or have little hope of recovery (0% and NNT=infinity).
- Calculations of effectiveness in cancer treatment, taking 10 year survival as the benchmark achievement (recovery is not a consideration), range approximately from 0.1% to 5% with a mean at 1% (NNT=100).
- These effect sizes for cancer treatment are much lower than those achieved by psychotherapy and psychological therapies (NNT=7 to NNT=2)
- Additionally the number of new cases each year for cancer treatment in the UK are 20% lower than those who might require psychotherapy and psychological therapies. However the cost per case for cancer treatment is perhaps as much as 4.5 times larger than for psychotherapy and psychological therapies. In contrast psychotherapy and psychological therapy services receive perhaps as little as 3% of the amount of funding received by cancer treatment services.
- This difference in funding means that although all new cases of cancer can access treatment only 10%-15% of new cases who can potentially can access treatment.

Big Box, Little Box

- Why is a big box considered to be better than a little box?
- Why are large scale studies considered to be better than small scale studies?
- Why are large sample sizes considered to be better than small sample sizes?

> Large scale studies and very large sample sizes are less effective and efficient at producing evidence of effectiveness and efficacy than small scale studies and small sample sizes.
> *Tim (Aaron) Beck*

- Power calculations for most situations where we are planning an effectiveness/efficacy trial of a psychotherapy almost always tell us that a minimum sample size of between 25 and 40 (50-80 in an RCT) will be sufficient.
- Larger study and sample sizes add recruitment difficulties, increase organisation complexity, introduce confounding factors, make it harder to manage data collection and to control data loss. They have produced spectacular and costly failures and frustrated funding agencies and universities.

How else might we know we are doing good and being effective?

Routine Outcome Evaluation and Local Effectiveness Research

- In the last 5-10 years we have seen a particularly steep rise of interest in change mechanisms, and mediators of change.
- This can be seen as, in part, as a reaction to a plateau in momentum, progress and funding in cohort studies, case series trials and randomised controlled trials.
- At the same time we have seen an increase of interest in the use of routine, session-by-session outcome measures. Go
- And similarly we have also seen an increase and normalisation in the use of video recording of clinical sessions. Go
- Individual practitioners can make use of routine, session-by-session outcome measures and session-by-session video recordings as components in supervision and personal research. Practitioners can examine whether or not they are 'doing good' for their patients, they can study their 'effectiveness' with patients, and through 'Deliberate Practice' (Rousemaniere, 2017; Miller, 2015) they can embark on improving their 'effectiveness'. Go
- Practitioners in collaboration with other practitioners can use routine, session-by-session outcome measures and session-by-session video recordings as a route to case series clinical trials and process-outcome research. These collaborations can research what is 'doing good' for patients, and how advances can be made in 'effectiveness'. Go

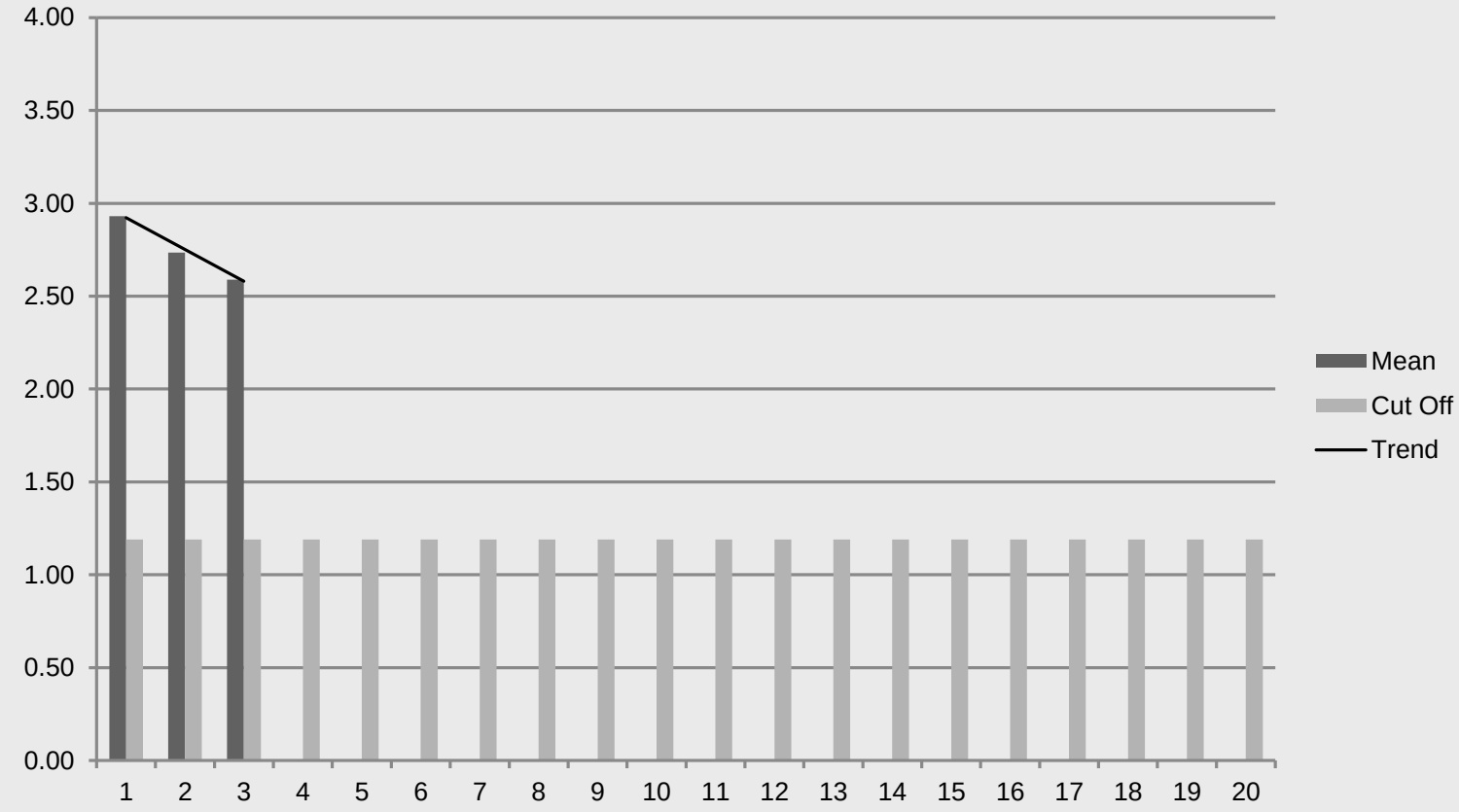
This is an ethical issue in 'doing good with integrity' and achieving 'effectiveness'

Lessons in the Use of Outcome Measures

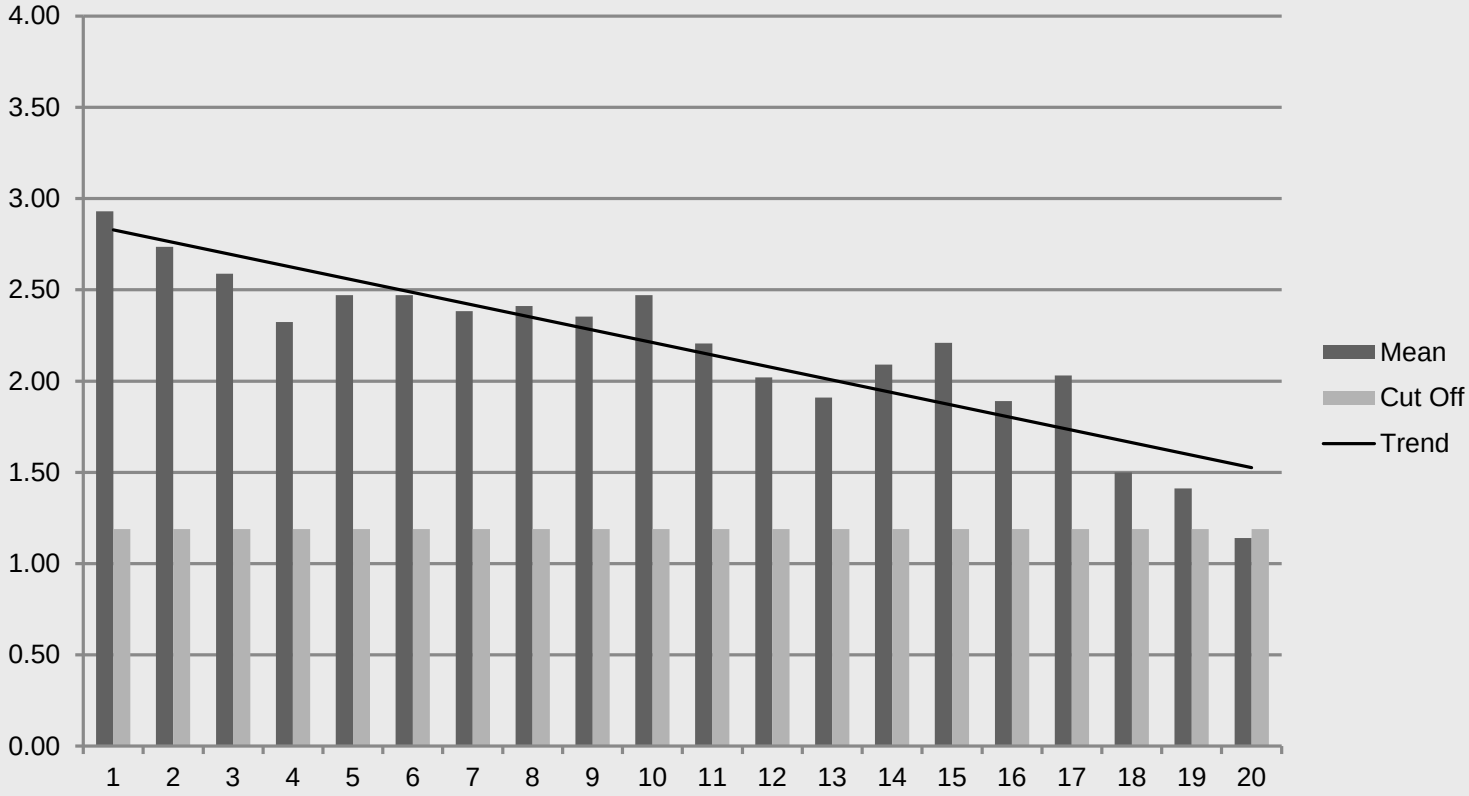
- Generally early improvers (responders) are long term improvers (responders).
- Generally improvement (treatment response) progresses in sudden or stepped gains.
- Generally therapists are poor at subjectively determining improvement and deterioration, session by session, in their patients.

(Crits-Christoph, 2001; Haas, 2002; Lambert, M. 2005; Whipple, 2003)

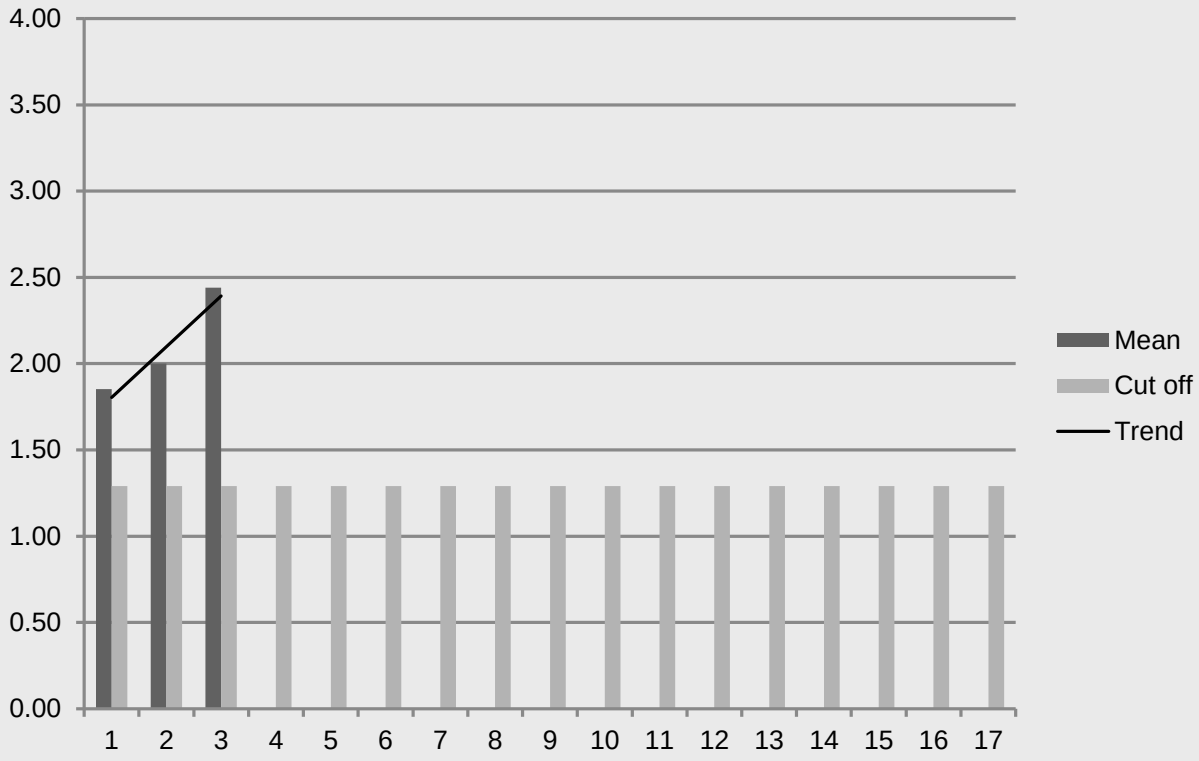
CORE-OM for Patient 8: The First Three Sessions



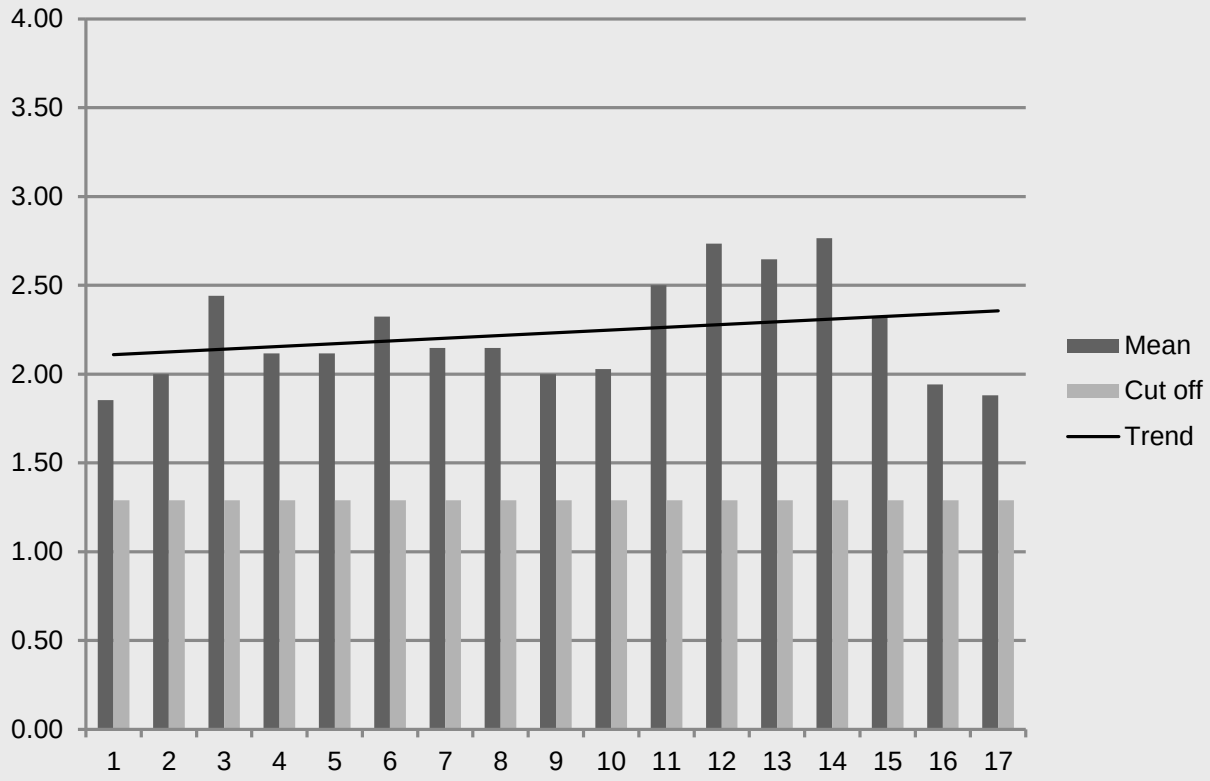
CORE-OM for Patient 8: Completed Treatment



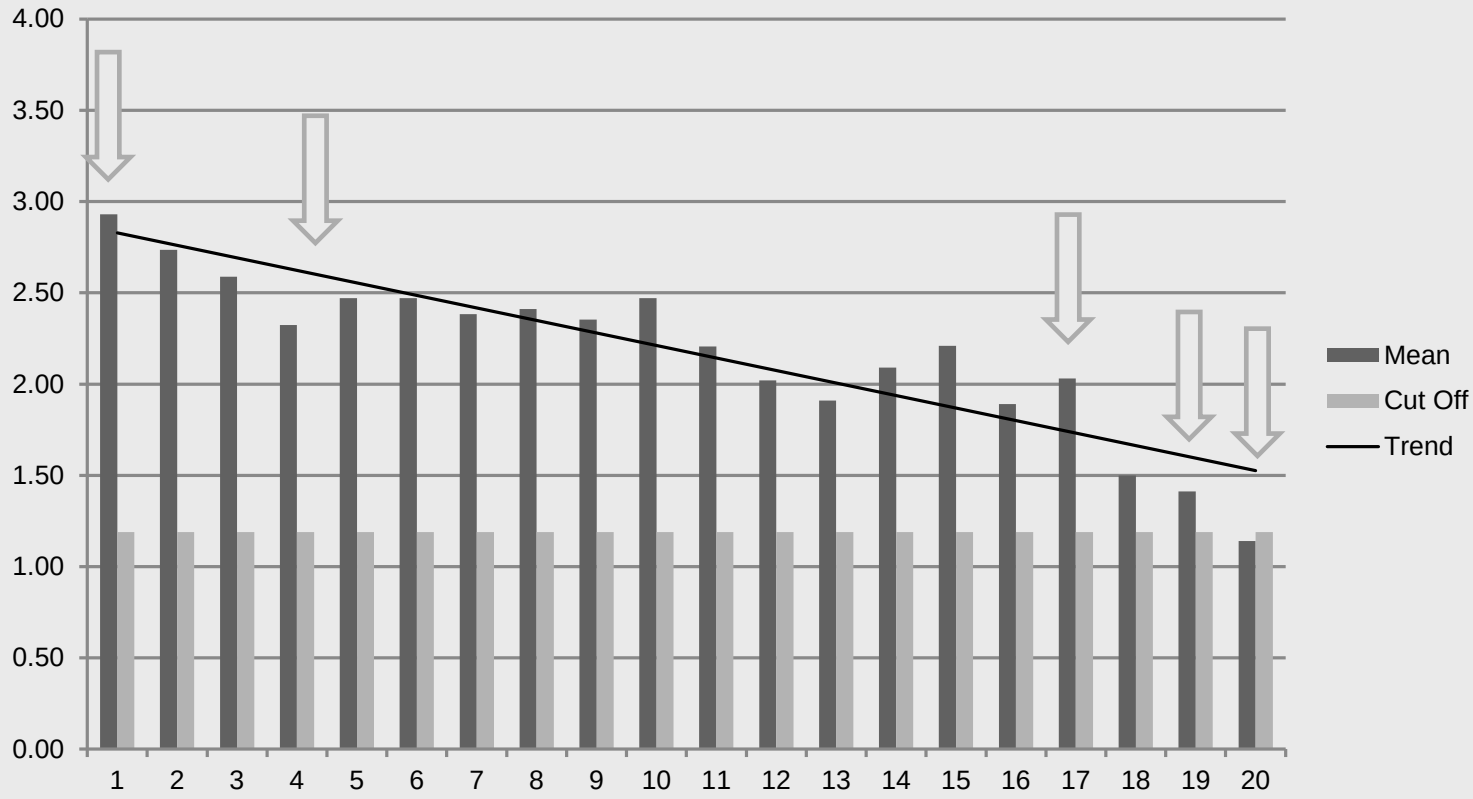
CORE-OM for Patient 32: The First Three Sessions



CORE-OM for Patient 32: Completed Treatment



CORE-OM as an Event Indicator for Patient 8



Methodological Issues in Local Effectiveness and Process-Outcome Research

- Collection and collation of a data set
  - Session by session outcome measures
  - Session by session video recordings

- Technology
  - Database for recording outcome measures and delivering session by session feedback to clinicians
  - Video cameras
  - Video editing
  - Archiving, Cataloguing, and Storage of video recordings

- Session and Time sampling
  - Within session and between sessions
  - Whole session or sampled sessions
  - Sampling: beginning, middle or end
  - Segmenting sessions: 1, 5, 10 minute segments or ‘event defined’ segments

- Selecting and developing research rating tools that are congruent with the clinical method

- Methods for case analysis with detailed examination of each session through triangulation of outcome scores with event rating of session video recordings

What do patients say about effectiveness?

When we work with patients, and we interact with them in other settings such as user groups, knowledgeable user projects, and as expert users, there is one mantra we repeatedly hear:

I want symptom relief ……

……and I want it now!

‘Effectiveness’ is an ethical issue in ‘doing good with integrity’

Summary and Conclusion

- Virtue ethics, which is the main pillar of our professional ethics and codes, lays an emphasis on ‘doing good with integrity’.
- A development from this embraced ‘evidence based practice’ and then ‘effectiveness’ as ways in which ‘doing good’ can be expressed.
- Psychotherapy research, as we find it in published studies, has shown good progress in many areas in demonstrating what therapies might be effective in specific circumstances.
- However there has been considerable difficulties in maintaining progress, including a failure of some large, funded research studies and problems in identifying change mechanisms and mediators.
- There are many ways in which formal research as got into difficulties, and been misunderstood
- It has been argued that a plateau in momentum, and progress has developed, and this is mirrored in a trend towards less funding for formal psychotherapy research projects.
- As a result there has been an increase of interest in small scale research using routine outcome evaluation and video recording for process-outcome investigation.
- This small scale research can emerge in the work of individual practitioners, and through collaboration between practitioners.
- We can see that there is a relationship between an ethical position in ‘doing good’ and seeking ‘effectiveness’ as both practitioners and researchers.

Last Slide

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