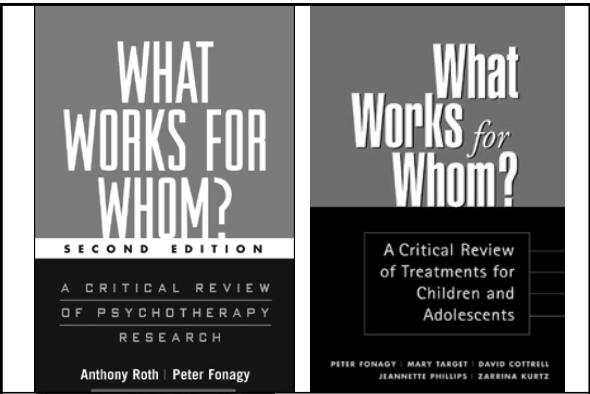



Aligning Evidence and Practice: A Key Challenge for 21st Century Child Psychiatry

Peter Fonagy
University College London &
The Anna Freud Centre

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P.Fonagy@UCL.AC.UK

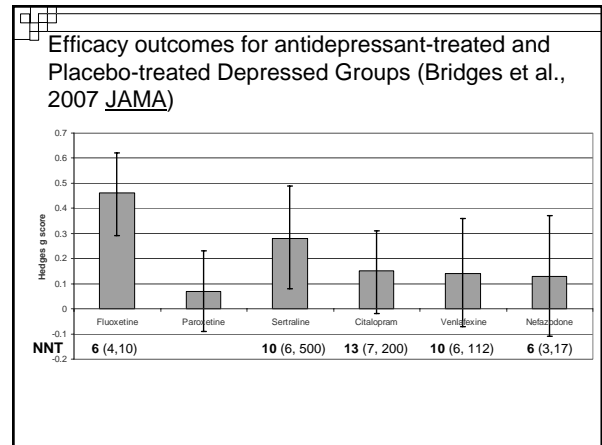



Two books that perhaps claim more than they can deliver




The progress associated with evidence based medicine

- Move away from “do this, do that” medicine to “why to do this or that”
- The intent is to increase certainty at the expense of intuition and unsystematic clinical experience by strengthening the grip on cause-effect relationships
- The main tool is the ‘hierarchy of evidence’ based essentially on the methodological character of studies rather than on their quality
- ‘While evidence-based approaches can improve *de rigueur* medical practice, “evidence-based” should not be understood to be synonymous with “best practice” in all relevant respects’ (Goldenberg, 2006, *Soc. Sci. & Med.*)

Brief summary of the achievements of evidence based medicine

- More precise research and practice oriented questions to answer
- Expanding cause-effect reasoning from laboratory analysis to improvements due to interventions
- Regrouping experiences from multiple sources (meta-analysis, systematic reviews)
- Assessment of the magnitude of effects of beneficial and noxious factors (NNT & NNH)
- Structuring literature search, findings and critical appraisal and dissemination



Definition of Evidence Based Medicine

- “Evidence based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett et al., 1996)
- Most EBM definitions are motivational, persuasive and essentialist rather than reportive, stipulative and operational

Psychotherapies are Identified as an Empirically Supported Treatment If:

- treatment has been **compared either to a no-treatment control group or some other intervention** (e.g., standard, routine care, treatment as usual for the setting)
- the treatment is **statistically significantly different** in outcome from this other condition,
- **two or more randomized controlled** studies attest to the effects of treatment,
- the studies include replication of the findings **beyond the original investigator** or originator of the treatment,
- the patient sample has been **well specified** (inclusion, exclusion, and diagnostic criteria), and
- treatment **manuals** were used to guide the intervention(s)

Some distinguished pioneering warnings

- “Between measurements based on RCTs and benefit . . . in the community there is a gulf which has been much under-estimated”
 - A L Cochrane, 1971
- “At its best a trial shows what can be accomplished with a medicine under careful observation and certain restricted conditions. The same results will not invariably or necessarily be observed when the medicine passes into general use.”
 - Austin Bradford Hill, 1984

RCTs and external validity, applicability, or generalisability

- Randomised controlled trials (RCTs) and systematic reviews are the **most reliable** methods of determining moderate treatment effects
- They must be **internally valid** (i.e., design and conduct must keep to a minimum the possibility of bias)
- **BUT:** to be clinically useful the result must also be relevant to a **definable group** of patients in a particular clinical setting

Main meta-analyses of child therapy RCTs

- Casey and Berman (1985)
 - 1952 to 1983, aged 12 and younger,
 - ES was .71 (76% treated>untreated)
- Weisz, Weiss, Alicke & Klotz (1987)
 - 1952 to 1983, age 4-18,
 - ES was .79 (79% treated>untreated)
- Kazdin, Bass, Ayers & Rodgers (1990)
 - 1970 to 1988, ages 4-18
 - ES was .88 (81% treated>untreated)
- Weisz, Weiss, Han, Granger & Marton (1995)
 - 1967 to 1993, ages 2-18
 - ES was .71 (76% treated>untreated)
- Weisz, Doss & Hawley (2005)
 - 1962 to 2002, ages 2-18
 - 236 studies testing 383 treatments including 427 treatment-control comparisons

Some evidence based treatments

- Anxiety and related conditions
 - Modelling, Reinforced exposure, CBT
- Depressive symptoms and disorders
 - CBT, Interpersonal therapy, activation therapy
- ADHD and related problems
 - CBT, relaxation and biofeedback training, behavioural parent and teacher training
- Conduct-related problems and disorders
 - Youth focused operant treatment, CBT (problem-solving skills), behavioural parent training, multisystemic therapy

Treatment Techniques Incorporated into Effective Therapies for Depression

- Promoting competency > 100%
- Self-monitoring > 89%
- Addressing relationship skills > 89%
- Communication training > 67%
- Child psychoeducation > 67%
- Problem solving > 67%
- Cognitive restructuring > 67%
- Improving parent-child relationship > 44%
- Relaxation > 44%

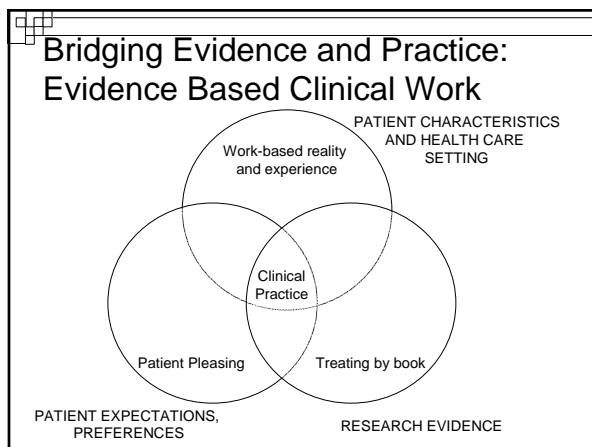
McCarty & Weisz (2007) JAACAP

Treatment Process Variables Predicting Outcome and/or Dropout from Treatments

- Perception of therapist as not invested in the child and/or parent (Shirk & Karver, 2003)
- Perception of therapist as not competent (Garcia & Weisz, 2002)
- Therapeutic alliance with child and/or parent (Hawley & Weisz, 2005)
- Creating sense of hopefulness about the treatment (Karver et al., 2005)
- Behavioral participation outside therapy sessions (McCarty & Weisz, 2007)

Dissemination of Evidence Based Therapies

- Most EBTs are CBT or behavioural
 - Most everyday clinical practice with youths is non-behavioural (eclectic, systemic and psychodynamic) (Ho et al., 2007; Martin et al., 2007)
- Clinical trainings of psychologists and psychiatrists
 - Evidence based treatments taught less than 10 years ago (Woody et al., 2005) – 1993: 11/22 EBTs; 2003: 5/22 EBTs
- UK ACAMH survey (2006) CBT is dominant approach of only 20% of respondents.



Evidence of the neglect of consideration of external validity of RCTs and systematic reviews

- **Research into internal validity** of RCTs and systematic reviews far outweighs research into how results should best be used in practice.
- **Rules** governing the performance of trials, such as good clinical practice, do not cover issues of external validity.
- **Drug licensing bodies**, such as the US Food and Drug Administration, do not require evidence that a drug has a clinically useful treatment effect, or a trial population that is representative of routine clinical practice.
- **Guidance** on the design and performance of RCTs from funding agencies, such as that from the Medical Research Council makes virtually no mention of issues related to external validity.

Evidence of the neglect of consideration of external validity of RCTs and systematic reviews

- Guidance from **ethics committees**, such as that from the Department of Health, indicates that clinical research should be internally valid, but makes no explicit recommendations about the need for results to be generalisable.
- Guidelines on the **reporting** of RCTs and systematic reviews focus mainly on internal validity and give very little space to external validity
- There are **no accepted guidelines** on how external validity of RCTs should be assessed.

Establishing Cause-Effect in RCTs

- Influences of bias eliminated in RCTs by
 - blinded treatment allocation,
 - placebo control
 - exclusion of patients or clinicians who have strong treatment preferences by getting consent
- Consequence for generalizability
 - underestimation of the benefits of treatment in clinical practice
 - especially for patient centered outcomes

Patient preference in early breast cancer

- Early breast cancer sufferers have a strong preference for
 - lumpectomy **OR**
 - the removal of the cancer by a mastectomy
- Only women who did not have a strong preference for a particular treatment can be recruited into the relevant RCTs
 - Can be as few as 10% who agree to have their treatment chosen at random
- If RCTs show a major advantage for one treatment, then external validity is not a problem.
- When one treatment is only moderately more effective but the patient has a strong personal preference for the slightly less effective option.
 - Would the results of the breast surgery RCTs, particularly in relation to psychological wellbeing, have been the same if such patients had been randomised?

The Culture and RCTs

- National and cultural differences
 - In diagnosis and admission rates
 - In the speed with which patients are investigated
 - In profile of problems associated with MDD
 - European trial of psychotherapy or family therapy for MDD in childhood or adolescence (Trowell et al, 2007)
- Differences between countries in methods of diagnosis and management
 - Prevalence of pediatric bipolar disorder (US vs UK)
 - Routine dispensing of stimulants for ADHD (US/UK vs Europe)
- Striking national differences in the use of ancillary so-called non-trial treatments
 - Quality of social supports and services available in Northern Europe vs. UK

Selection of Clinicians and Clinics

- In some systematic reviews all RCTs were based solely in university clinics
 - Treators in RCTs differ in terms of professional goals and work pressures (time, productivity, financial)
 - Clinicians cannot afford to specialise on single problem and treat broad array of problems on same day
- In some trials therapists with poor outcomes are routinely rejected at the outset
 - Further those who had adverse treatment outcomes are excluded → The benefit from treatment due largely to the consequently reduced probability of iatrogenic effect
 - Specially selected therapists for RCTs
- EBTs involve learning and following a manual
 - Takes away from spontaneity but also difficult to deliver spontaneously
 - Learning evidence based assessments
- The staff therapists who provide therapy (do not know treatment developer, were told to train in the method)
- The setting of usual care different world from RCTs (more forms to complete, less welcoming approach)

Selection of Patients: Eligibility

- Selection before consideration of eligibility
 - The proportion of patients with a particular disorder in the local community served by a participating centre who are considered for recruitment into a trial will often be well below 1%
- Selection by eligibility criteria
 - Excluded patients by **age**
 - RCTs also exclude patients with highly prevalent **comorbidity and family adversity**.
 - Exclusion rates can be very high
 - A review of 41 US National Institutes of Health RCTs found an average exclusion rate of 73%

Selection of Patients: Bias by Exclusion

- Bias in terms of psychological and social characteristics (more severely disturbed, comorbid, miss appointments, drop out of treatment)
- Characteristics of families (parental psychopathology, family life event stressors, child maltreatment)
- Reasons for seeking treatments (not recruited through ads or screening but referred by desperate caregivers or court – only 13% across studies)

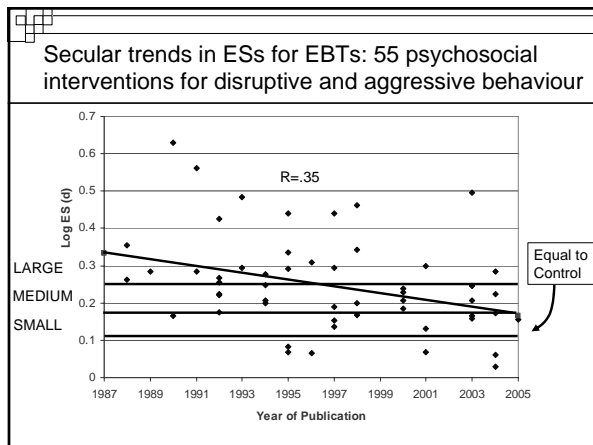
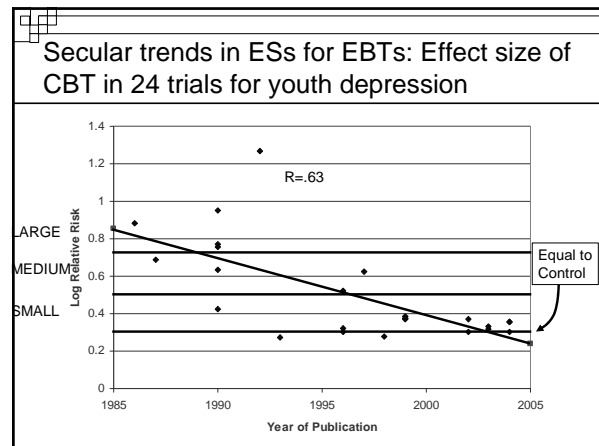
Selection of Patients: The Cinderella Groups

- Gaps in coverage of problems
 - Few RCTs of anorexia (none of bulimia)
 - Annual mortality is 12x above 15-24
 - Bulik et al. (2007) 32 studies of AN (13 too poor in design, 8 medication, 7 family therapy, 3 CBT, 1 CAT, 1 psychoanalytic, 1 supportive but mostly for adults)
 - Substance abuse in youths
 - Particularly harder drugs
 - ADHD in adolescence
- 150 DSM diagnoses that can be applied to youths
 - EBTs cover only a small selection of these

Comparison of EBT trials and real life

- Only 13% of study samples clinically referred
- Only 19% employed at least one practising clinician.
- In only 4% of studies was treatment provided in an actual service setting separate from the research
- Only 1% of studies include at least one practising clinician, clinically referred children and some treatment carried out in a service setting.
- **But**
 - This pattern is changing, increased emphasis on “effectiveness” (vs. “efficacy”) in trials

(Weisz, et al., 2006, Am. Psych.)



EBT trials compared with usual care

- EBTs compared with usual care have reduced ESs
- ES of 32 RCTs of 36 EBTs
- Mean = .30 (95% CI: -.03, .63)
- 62% of EBT treated patients are better off than average normally treated child
- Only 22% of ESs medium or large (<.5)
- 38% small (.2-.5)
- 41% negative or insignificant

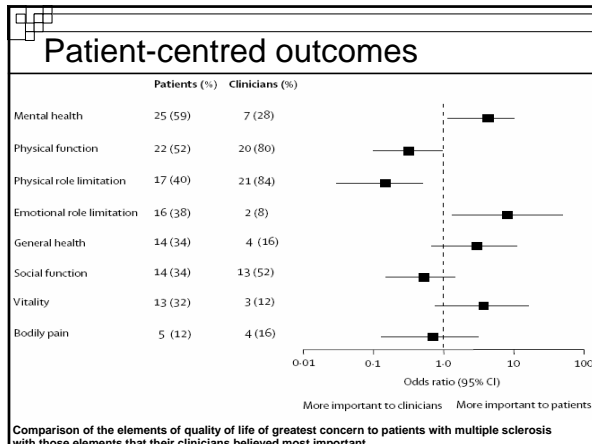
(Weisz, et al., 2006, Am. Psych.)

Studying usual care with care

- Writing up (manualising) particularly effective usual care protocols
- Careful study of the implementation of EBTs (clinician adaptation, clinician selection, coaching, recipient and organisational preparation) (Fixsen et al., 2005, National Implementation Research Network)
- Psychosocial interventions normally tested on pharmacology models (Successive Efficacy Trials or SET)
 - lab, then efficacy studies under idealised conditions, then effectiveness studies under ‘average’ conditions
- Weisz et al. (2006) deployment trial where manual for treatment is developed in practice context

Outcome Measures and Follow-up

- The outcomes **not** always **clinically relevant**
 - Surrogate outcomes (e.g. public speaking anxiety)
 - o of questionable clinical relevance,
 - o surrogate outcomes are often misleading
 - **Arbitrary scales** (e.g symptom scales)
 - o a review of 2000 RCTs in schizophrenia identified 640 scales, many of which were devised for the particular RCT and had no supporting data for validity or reliability
 - o unvalidated scales were more likely to show significant treatment effects than established scales.



- ### “Depression Reduced With Brussels Sprouts.”
- “Self-report ratings of depression indicated change and support the proposition”
 - How much change in depression occurred beyond that demonstrated by the measure?
 - Does change relate to how individuals are doing in everyday life?
 - More we believe in BST for depression more likely we are to lose sight of the actual metric.
 - Depression actually has many referents to which the arbitrary metric could be linked (e.g. changes in eating or weight; crying; staying in bed during time ordinarily devoted to other activities; and interacting less with peers).
 - We are not sure that any of these changed.
 - Measures are arbitrary but we reify them, we treat them and think of them as if they were not.

- ### Key Points About Assessment and Arbitrary Metrics
- Measures reflect arbitrary metrics if the connections between the observed score and the true score on the underlying dimension are not known.
 - Height, weight, or income are not arbitrary,
 - Marital satisfaction, depression, and self-esteem on self-report inventories or interviews
 - Reliability and validity do not resolve the arbitrariness of a metric.
 - Small or large amounts of change on a measure with an arbitrary metric does not necessarily reflect small or large changes on the underlying construct.

- ### Common Factors vs Specific Techniques
- Is therapeutic relationship more important than specific techniques?
 - Children treated with *Coping Cat* rate their relationship with the therapist as most important aspect of their treatment (Kendall & Southam-Gerow, 1996)
 - Controversy in adult literature in practice based evidence what proportion of variability therapist accounts for
 - Manuals provide no indication of how to get child to like you
 - What we need to know?
 - What is a positive therapeutic relationship?
 - What therapist behaviours foster it?
 - Can it be taught/trained to enhance effectiveness?

- ### Narrow vs Broad Treatment Approach
- Should treatment be focused on single problems or address problems in clusters or the whole child?
 - Narrow approach
 - provides useful context for testing treatments without interference from unwanted conditions (but felt irrelevant by clinicians)
 - Appears more effective in meta-analyses (but perhaps not because of breadth of applicability but breadth of technique)
 - Co-occurrence of problems is norm not exception in both community and clinical samples (Angold et al., 1999)
 - The need to reverse the trend for specific therapies and create effective generic but focused treatments which pertain to single critical capacity (self-esteem, mentalization, affect regulation)
 - MBFT (Asen, Target, Fearon, Williams, Bleiberg, Fonagy)
 - Integrative Multimodal Practice (Bevington, Fuggle, Asen, Target, Fonagy)

- ### Mechanisms of change underlying treatment benefit
- We know more about what outcomes treatments produce than what causes outcomes (Kazdin, 2000)
 - In absence of understanding causal mechanisms → superstitious multiplication of therapies (currently in excess of 500)
 - e.g. Both multisystemic therapy and therapeutic foster care programs work to the extent that affiliation with delinquent peers is reduced (Huey et al., 2000; Eddy & Chamberlain, 2000)
 - Benefits of understanding mediators
 - Addressing impediments, stalls and failures of therapy
 - Training therapists to focus on key targets (not techniques)
 - Cross-cutting principles to combining, redesigning and refining interventions

Gaps in Outcomes Research

- No good evidence for who will benefit from what type of psychotherapy
- 'Inexact therapies' → partial effectiveness
- 'Attachment to methods' → 'guildification' of interventions

New Intellectual Framework for Psychotherapy

- Developmental studies of adult psychopathology → identifying psychological and neural mechanisms underlying disturbance
- We need therapeutic techniques specifically designed to address a developmental dysfunction
- Develop treatments in the setting in which they are to be used (DFM – deployment focused model)
- Continuous monitoring of treatment impact
- Consensus concerning impact of social relationships

New APA Task Force Definition of EBP (APA, 2006)

- *Evidence-based practice in psychology* (EBP) is the integration of the **best available research** with clinical expertise in the context of patient characteristics, culture, and preferences.
- EBP articulates a decision-making process for **integrating multiple streams of research evidence**—including but not limited to RCTs—into the intervention process.

EBP vs. ESTs

- **EST**: Does a treatment work for a certain disorder or problem under specified circumstances.
- **EBP**: What research evidence (including relevant results from RCTs) will assist the psychologist in achieving the best outcome for a specific patient.
- **ESTs** are specific psychological treatments that have been shown to be efficacious in controlled clinical trials
- **EBP** encompasses a broader range of clinical activities (e.g., psychological assessment, case formulation, therapy relationships).

EBP: Best Available Research Evidence

- *Clinical observations* → innovations and hypotheses
- *Qualitative research* → subjective, lived experiences
- *Systematic case studies* → comparing patients
- *Single-case designs* → causal relationships
- *Public health and ethnographic* → availability, utilization, and acceptance of mental health treatments
- *Process-outcome* → mechanisms of change
- *Interventions as delivered* → ecological validity of treatments
- *RCTs* → causal inferences about the effects of interventions

Dimensions of Interventions in EBP

- **Effectiveness** – does the treatment work?
- **Clinical Utility** – the applicability, feasibility, and usefulness of the intervention in the local or specific setting where it is to be offered.
 - effects across varying and diverse patients, therapists, settings,
 - the robustness of treatments across various modes of delivery;
 - the feasibility with which treatments can be delivered to patients in real world
 - the costs associated with treatments.

Patient's Theory of Illness and Cure

- Culture influences
 - Nature and expression of pathology
 - Understanding of psychological health and illness
 - Patterns of seeking, using and receiving help
 - Presentation and reporting of symptoms and desired outcomes
- As psychotherapy is collaborative enterprise in which patient and clinician negotiate ways of working together → patients' values and preferences are central components of EBP
 - Must ensure patients understand costs and benefits
 - Maximise patient choice between effective treatments

Consensus of EBP Task Force

- "In a given clinical circumstance, psychologists of good faith and good judgment may disagree about how best to weigh different forms of evidence; over time, we presume that systematic and broad empirical inquiry—in the laboratory and in the clinic—will point the way toward best practice in integrating best evidence" p.280.
 - APA (2006) *American Psychologist*, 61, 271-285.

Conclusion

- Science IS good for practice
 - Which form of care is best for children
 - What causal mechanisms play a role
 - What circumstances can interfere with a treatment working
- But practice is also excellent for science
 - Where knowledge is most needed
 - Ground science in everyday clinical care

And another pioneering warning

- 'Science is built up with facts as a house is with stone but a collection of facts is no more a science than a heap of stones is a house'
 - Jules Henri Poincaré



For Electronic version please e-mail: P.FONAGY@UCL.AC.UK