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EVIDENCE-BASED VERSUS EFFECTIVENESS STUDIES: THE RANDOMIZED CONTROLLED TRIAL AND PSYCHOTHERAPY RESEARCH

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DISCLOSURES

- I am the Scientific Editor of the NEA-BPD scientific website.
- I receive royalties from the American Psychiatric Press and Cambridge University Press
- I am one of 3 Co-editors-in chief of *Personality and Mental Health*, a journal owned by Wiley-Blackwell (no income)
- I have no financial relationships with any pharmaceutical or device company
- I do not directly own stocks in pharmaceutical or device companies
- I may talk about the off-label use of psychiatric medication

THE PRIMARY INTERVENTION IN PATIENTS IS ALWAYS TREATMENT *PLUS* MANAGEMENT

- Patients with BPD have a poor sense of limits or boundaries
- Patients with BPD often make decisions utilizing their emotional mind rather than their rational or wise mind and when emotional, their sense of boundaries or respect for limits dissolves
- Thus structure helps patients with BPD stay “focused” on that task and can corral the emotional mind somewhat
- All successful BPD (psycho)therapies are structured (even psychodynamic ones)
- Encouraging the patient into that structure or using the structure to help limit or focus the patient is what I call management

BPD PSYCHOPHARM: IMMEDIATE PROBLEMS

- **No medications carry a specific indication for use in treatment of personality disorders**
- **Thus all medications must be used “off label” though not uncommon to use medications off-label**
- **Medications for BPD are less effective than when used in other disorders**
- **BPD patients seem exquisitely sensitive to side effects**

A BRIEF TOUR THROUGH PSYCHOPHARMACOLOGY

META-ANALYSIS: PHARMACOTHERAPY FOR BPD CORE TRAITS (Nosè et al)¹

“..pharmacotherapy can exert a modest positive effect on specific core traits of BPD.... affective instability and impulsivity..... affective instability and, more specifically, against anger..... interpersonal relationships, and global functioning.”(p 352)

COCHRANE REVIEW: PHARMACOLOGICAL INTERVENTIONS FOR PEOPLE WITH BPD²

- [P]eople with BPD should know that this [medication] is not based on good evidence from clinical trials. This does not mean it may not do considerable good and there is no indication of significant harm. Largely, trials have been small, short, and poorly reported. (pp 19-20)

¹Nose M, Cipriani A, Biancosino B, et al. Efficacy of pharmacotherapy against core traits of borderline personality disorder: meta-analysis of randomized controlled trials. *Int. Clin. Psychopharmacol.* 2006;21:345-353.

²Binks CA, Fenton M, McCarthy L, et al. Pharmacological interventions for people with borderline personality disorder. *Cochrane Database Syst. Rev.* 2006:CD005653.

A BRIEF TOUR THROUGH PSYCHOPHARMACOLOGY

WFSBP GUIDELINES³

“Urgent necessity to conduct more controlled studies of good quality..[with] more drug trials that focus on the improvement of affective instability...”

We need to use safe drugs and thus should we use lithium, irreversible MAOIs, TCAs

No evidence for “length” of psychopharm treatment

DUGGAN ET AL REVIEW⁴

“High-quality evidence of efficacy...is lacking and “[while] there is now some encouraging evidence in support...this evidence remains weak.”

³Herpertz SC, Zanarini M, Schulz CS, et al. World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for biological treatment of personality disorders. *World J. Biol. Psychiatry.* 2007;8:212-244.

⁴Duggan C, Huband N, Smailagic N, et al. The use of pharmacological treatments for people with personality disorder: a systematic review of randomized controlled trials. *Personality and Mental Health.* 2008;2:119-170.

NICE* STUDY IN THE UK (Psychopharmacological treatment)

- Used essentially the same studies (27) that these other studies used
- They find:
 - Too few studies of a given drug across given settings (outpatient, inpatient, partial hospitalizations)
 - Too many outcome measures being used across different studies or within a study
 - One measure used for many different outcomes
 - Too small numbers of subjects in the studies
- **Drug treatment should not be used specifically for BPD or for the individual symptoms or behavior associated with the disorder.**

*National Institute for Health and Clinical Excellence (CG 78, Jan 2009)

NICE* STUDY IN THE UK (Psychotherapeutic treatment)

- **When providing psychological treatment for people with borderline personality disorder, especially those with multiple comorbidities and/or severe impairment, the following service characteristics should be in place:**
 - **an explicit and integrated theoretical approach used by both the treatment team and the therapist, which is shared with the service user**
 - **structured care in accordance with this guideline**
 - **provision for therapist supervision.**
- **Although the frequency of psychotherapy sessions should be adapted to the person's needs and context of living, twice-weekly sessions may be considered.**
- **Do not use brief psychotherapeutic interventions (of less than 3 months'**

*National Institute for Health and Clinical Excellence (CG 78, Jan 2009)

NICE* STUDY IN THE UK (Psychotherapeutic treatment) (Cont'd)

- **When providing psychological treatment to people with borderline personality disorder, monitor the effect of treatment on a broad range of outcomes, including personal functioning, drug and alcohol use, self-harm, depression and the symptoms of borderline personality disorder.**
 - (That management idea again.)

APA GUIDELINES (2001)

- **“clinical experience suggests that most patients with borderline personality disorder will need extended psychotherapy to attain and maintain lasting improvement in their personality, interpersonal problems, and overall functioning. Pharmacotherapy often has an important adjunctive role”**

APA: Practice Guideline for the Treatment of Patients with Borderline Personality Disorder. *Am J Psychiatry (Suppl)* 2001; 158(10):1-52.

THE VARIOUS PSYCHOTHERAPIES: RCT EVALUATED

- **Cognitive-Behavioral**
 - CBT
 - DBT
 - Schema Therapy
- **Psychodynamic**
 - Mentalization-Based
 - Transference-Focused
 - (Schema Therapy)

HOW TO DECIDE WHICH ONE TO USE

- **Though all are manualized, some are more structured (and manualized) than others**
 - **More structured are the DBT Therapies**
- **Though all are manualized, some are more transferential**
 - **But even this does mean a cold, distant therapist**

NO MATTER WHAT THE ULTIMATE THERAPY

- **Patient must make a commitment to the process of therapy (this is not just for DBT)**
- **Patient must make a commitment to the length of the therapy**
- **Discussion of resources and payment**
 - **Motivational interviewing may help to make commitment**

EFFICACY VS EFFECTIVENESS

- **Efficacy** – the randomized controlled trial
 - High internal validity but it is generalizable?
- **Effectiveness** – study of the more natural “setting” of the intervention
 - High external validity but not as well-controlled with more limitations
- Both benefit the patient
- Cost effectiveness involves the interface of these two concepts because an efficacy study may not be cost-effective, i.e. practical to implement
 - There have been studies of the cost effectiveness of the interventions here, especially the behavioral interventions

TRANSLATING THE RCT

- **What is statistically significant may not be clinically significant.**
- **What is statistically significant, may not be practically implemented.**
- **The “attention” given in an efficacy study may not reflect clinical reality and may impact outcome from both psychopharmacologic as well as psychotherapeutic trials**
 - **Placebo may be very powerful here or non-specific interventions**

SHOULD WE BE DIRECTLY COMPARING THESE TREATMENTS?

- A “possibility is that all roads lead to Rome-or at least a suburb in the vicinity of Rome. Could it be that any thoughtful, systematic approach to borderline personality disorder, based on our knowledge of the disorder, is potentially helpful, whatever its theoretical underpinning or technical approach?”¹
- “[W]e should derive great satisfaction in knowing that there are a number of different types of interventions that appear effective for borderline personality disorder. The greater the number of available interventions, the better the chance that a patients may be able to improve to a degree where she feels that life is once again, if it ever was, worth living.”²
- ¹ Gabbard GO. Do all roads lead to Rome? New findings on borderline personality disorder. *Am J Psychiatry* 2007; 164(6): 853-855
- ² Silk KR. Augmenting psychotherapy for borderline personality disorder: The STEPPS program. *Am J Psychiatry* 2008; 165(4):413-415.

GUNDERSON'S COMMENTS

(Am J Psychiatry, May 2009, p 536)

- **“....BPD] is the only major psychiatric disorder for which psychosocial interventions remain the primary treatment. Residents who go into psychiatry with an interest in personal involvements, in seeing themselves in their patient's experiences and their selves as therapeutic tools, now can find few other places in psychiatry to actualize these aspirations. Residents and other mental health professionals who make a serious investment in treating patients with BPD can expect to become proud of their professional skills and of their personal growth in tolerance and empathy and to experience a highly personal, deeply appreciated, life-changing role for their patients.” (p 536)**