First Do No Harm

Avoiding adverse outcomes in personality disorder treatments

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Outline

* Potential for harmful outcomes in treatment
  * Trials
  * Clinical practice
* Including negative outcomes when evaluating interventions
* Understanding how harm may be caused
* Guarding against causing harm

What are we talking about?

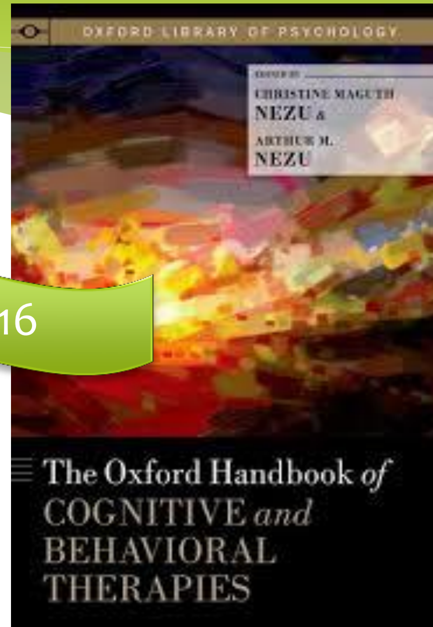
* Various terms –
  * Adverse events (used in research)
    * significant episodes during or shortly after treatment (e.g., suicide, hospital admissions)
  * Adverse effects
  * Deterioration
  * Negative effects
  * Side effects
    * Improvement on some outcomes, deterioration on others

Parry et al. (2016). Iatrogenic harm from psychological therapies – time to move on. *British Journal of Psychiatry, 208*, 210–212.

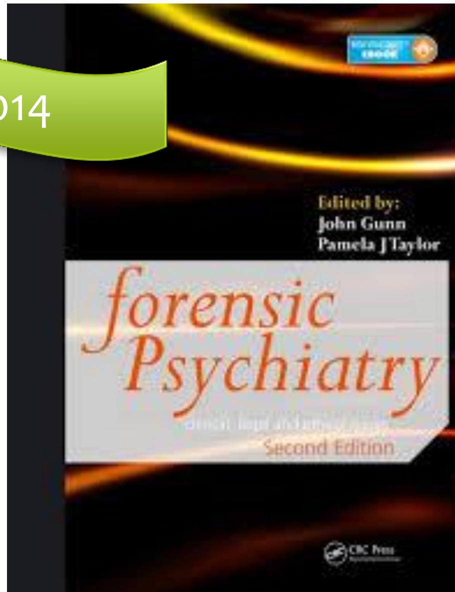
How important is this topic?

* Apparently, not very important if you look for these terms in the indexes of clinical handbooks

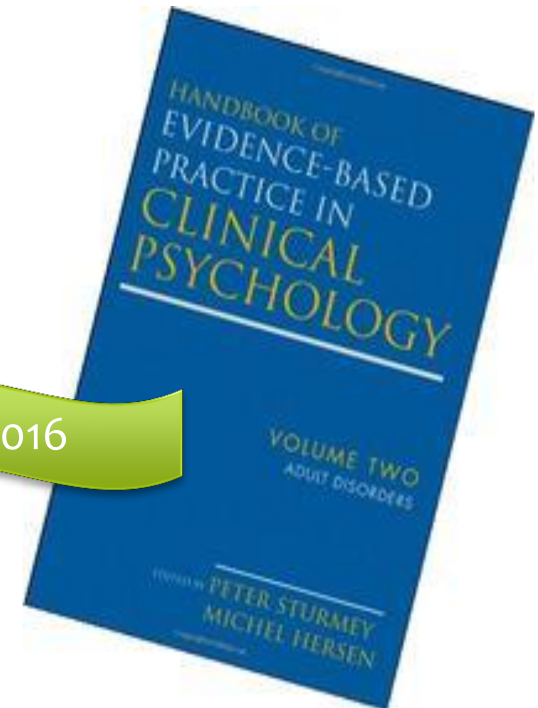
2016



2014



2016



Can treatment harm?

YES

Brandon Welsh
Professor of Criminology and Criminal Justice

First example of what harms

- Cambridge-Somerville Delinquency Prevention Study
  - 650 boys, aged 3-15
  - Matched pairs (age, IQ, social background/temperament)
  - Randomly assigned to treatment / no treatment
  - Treatment
    - case worker visits over average 5½ years
    - advice, guidance, teaching, activities, summer camp, onward referral

Powers, E., & Witmer, H. (1951). *An Experiment in the Prevention of Delinquency: The Cambridge-Somerville Youth Study*. New York: Columbia University Press.

First example of what harms

- Cambridge-Somerville Delinquency Prevention Study
  - At 9 years after the start of treatment more of the treatment group had been in court for more offences
  - At 30 years after the start of treatment, with 95% follow-up, those who were in the treatment group were more likely to have been convicted of serious crimes, died on average 5 years younger, and were more likely to have received a psychiatric diagnosis.
  - Negative effects were greater where there was more treatment.

McCord, J. (1978). A 30-year follow-up of treatment effects. *American Psychologist*, *33*, 284-289.

Later examples of what harms

* Scared Straight
  * Increased odds of offending
* Critical Incident Stress Debriefing
  * Higher PTSD and anxiety
  * Even though people find it helpful
* Drug Abuse Education
  * Can make drug abuse more likely

Lilienfeld, S.O. (2007). Psychological treatments that cause harm. *Perspectives on Psychological Science*, 2, 53-70.

Later examples of what harms

* A review of systematic reviews of harm recidivism) of delinquency prevention
* 8 of 15 reviews of treatments recorded
  * Scared Straight
  * Second Responder
  * Boot Camps
  * Drug courts
  * Prison-based drug treatment
  * Court mandated interventions for do
  * Anti-bullying programmes in schools
  * Custodial vs community sanctions

No harm:

- Cognitive-behavioural therapy
- Drug substitution
- Early parent/family training
- Mentoring
- Self control
- Serious juvenile offender programmes
- Non-custodial employment

Welsh, B.C. & Roque, M. (2014). When crime pr
systematic reviews. *Journal of Experimental Crim*

Later examples of what harms

* Systematic review of offender CBT treatment studies
* Completers vs Untreated
  * A positive effect in reducing recidivism (d = 0.11)
* Non-completers vs Untreated
  * A negative effect on recidivism (*d= -0.16*)
* Non-completers are *more likely* to be reconvicted than untreated

McMurran, M., & Theodosi, E. (2007). Is treatment non-completion associated with Increased reconviction over no treatment? *Psychology, Crime and Law, 13,* 333-343.

Measuring Outcomes

* In research and clinical practice, do we look equally conscientiously for positive and negative outcomes?
* Lilienfeld says that our evaluations are subject to
  * Positive outcome expectancies, and
  * Confirmation bias
* We look for positive outcomes because we expect and hope for positive change
* We fail to see deterioration.

Today's Purpose

What
can we do
better?

Trials

The PEPS Trial

* Psycho-Education and Problem Solving for adults with personality disorder

The PEPS Trial

The PEPS trial was funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (project number 08/53/06). The views and opinions expressed here are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health.

The PEPS Trial

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Psychoeducation with problem-solving (PEPS) therapy for adults with personality disorder: a pragmatic randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of a manualised intervention to improve social functioning

Mary McMurran, Mike J Crawford, Joe Reilly, Juan Delport, Paul McCrone, Diane Whitham, Wei Tan, Conor Duggan, Alan A Montgomery, Hywel C Williams, Clive E Adams, Huajie Jin, Matthew Lewis and Florence Day on behalf of the PEPS Trial Collaborative Group

The PEPS Trial

- Adults with personality disorder
- Recruited from community mental he… ices in 3 NHS Trusts in England & Wale…
- Two-arm RCT
- Intervention
  - Psycho-Education – up to 4 individual sessions
  - Problem Solving – 12 group s…
- Usual Treatment

A mainstream intervention – not something unconventional

Shown to work in a pilot study

Outcomes

* Primary outcome at 72 weeks
  * Social functioning measured by the Social Functioning Questionnaire
* Secondary outcomes
  * Mood (HADS)
  * Self-assessed problem severity
  * Scheduled/unscheduled service use (health records)
* Health economics
  * EQ-5D
  * Recorded service use

The PEPS Trial

Just when it was all going so well ….

Recruitment to the PEPS trial was stopped because more ‘adverse events’ observed in the treatment arm than in treatment as usual arm

“Stop recruiting!”

* Data Monitoring and Ethics Committee (DMEC), viewing unblinded data, identified a difference in AEs between arms as a safety issue
* Independent Trial Steering Committee (TSC) advised us to stop recruitment and treatment, but continue follow up
* Happened 30 months into recruitment, and 2 months before end of recruitment and 306 of the target 340 participants had been recruited (90%)

Adverse Events

* Defined in protocol as
  * Death for any reason
  * Hospitalisation for any reason
  * Any serious unexpected event
* In PEPS trial, AEs identified by:
  * asking participants during each contact (3 in 72 weeks)
  * asking for info from responsible clinician
  * writing to GP where there was loss to follow-up
  * ascertaining reasons for the event

What did we find?

* PEPS arm (n=152)
  * 117 adverse events from 60 people
  * Included 4 deaths
    * 1 suicide before treatment started
    * 1 cardiac arrest during treatment phase
    * 1 death by natural causes
    * 1 suicide during follow-up - No evidence of being related to the trial
* Usual treatment arm (n=154)
  * 76 adverse events from 39 people
  * No deaths

What did we find?

Risk is greater in PEPS

- Relative Risk (RR) = 1.52
- The ratio of the probability of an event occurring in the treated group : the probability of an event occurring in the untreated gr
  - RR 1 no c e
  - RR <
  - R d group

But has clinical significance

Not statistically significant

What happened?

* Bias?
* Follow up greater in the PEPS arm
* Did we find out more from those in PEPS arm?
  * More contact with therapists and researchers in intervention and follow-up
  * Participants may have felt more able to tell therapists and researchers about AEs
  * Clinicians may have been more likely t[...] PEPS participants so that we could de[...]

Accessing service use data from HSCIS

What happened?

Shows we need adequately powered trials to build on pilot studies

- Harm?
- In ITT analysis, no differences between arms on primary or secondary measures
- Outcomes were better for those who received PEPS per protocol
- PEPS was marginally more cost-effective

Suggests PEPS itself wasn't harmful

Participants' views

* Interview information suggests that PEPS was dissociated from ongoing good clinical care and management
* When PEPS ended, people felt unsupported
  * "I believe the spike in adverse events was due to the model not sustaining the support. It gave people help and then left them."
* After PEPS, may feel abandoned and have only damaging means of coping, or
* After PEPS, the only way to get furth dramatic gestures.

Risk may be from non-specific sources, e.g., service-related aspects

AE Categories	Usual Care (n=152)		PEPS (n	
	Events	Individuals	Ev	
Planned hospital admission	2	2	1	
Self-harm (inc. alc drug overdose)	27	16	42	24
Suicide/attempted suicide	4	3	7	7
Deterioration in mental health	3	2	9	7
Suicidal ideation	6	6	8	6

Type of self-harm is mostly distress related

Were we guilty of simply looking for adverse events when others do not?

How much attention is paid to adverse events?

* Duggan et al. examined all 82 NIHR-funded trials, 1995 – 2013

	Psychological	Drug	Combined	Other
AEs in protocol or report (n=82)	19/44 (43%)	11/14 (79%)	4/5 (80%)	11/19 (58%)

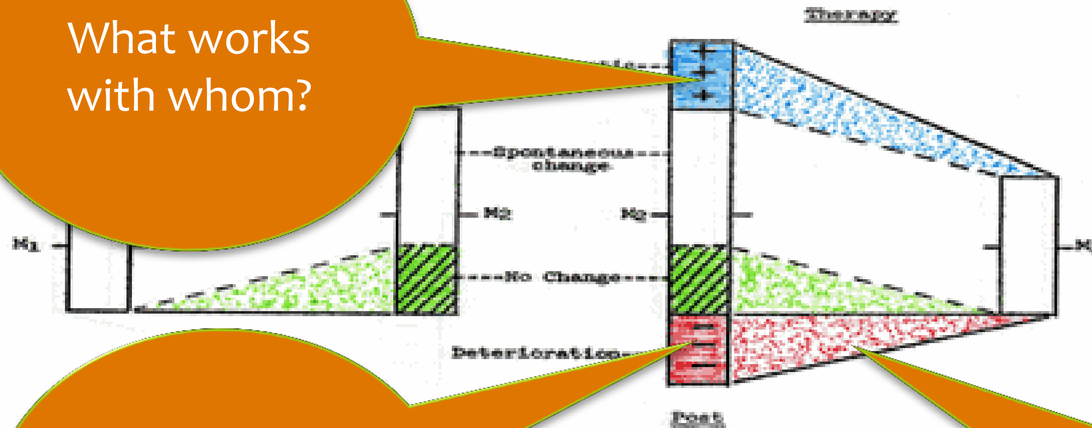
* Psychology trialists have not been as reporting adverse events
* AEs are more likely to be recorded in more recent studies

Should clinicians be equally assiduous?

Duggan et al. (2014). The recording of adverse events from psychological treatments in clinical trials: Evidence from a review of NIHR funded trials. *Trials* 15, 335.

The Deterioration Effect – Bergin (1966)

Figure 1
The Deterioration Effect: Schematic Representation of
Pre- ...st Distributions of Criterion Scores in
P... Outcome Studies



...er improvement, whereas minus signs indic...
...est mean criterion score; M_2 = posttest m...
...nplications of Psychotherapy for Therap...
Journal of Abnormal Psychology, 71, p. 2...
...an Psychological Association.

What works with whom?

What harms with whom?

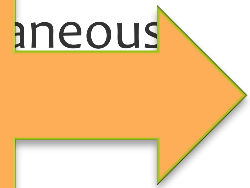
Even empirically supported therapies may harm some people

Clinical Practice

Causes of harm

- ‘Adverse events’ (AE) recorded in trials (death, hospitalisation) may be related or unrelated to the treatment
- Often it is difficult to tell
  - AE = hospitalisation
  - What for? A broken leg
  - How caused? An accident
  - True accident or deliberate self harm as a result of mental state deterioration?
  - If DSH, what this caused by treatme… aneous life event (e.g., relationship breakd…

Better ask the service users….



Patient-reported bad effects

* National survey, NHS England & Wales
* 220 services
* 14,587 individual respondents
  * adults in treatment for anxiety and/or depression
  * mainly cognitive-behavioural therapy
* 5% (n=763) reported lasting bad effects
* More likely if unsure of what therapy they received
* Less likely if they were given enough information about before it started
* More likely for ethnic minority patients and non hetero patients

Crawford et al. (2016). Patient experience of negative effects of psychological treatment: results of a national survey. *British Journal of Psychiatry, 208*, 260-265.

Need to know

* Only when we spot negative outcomes can we take corrective action
* In a counselling centre study, client progress /deterioration was measured by researchers
* Counsellors detected only 21% of the cases that had deteriorated.

Hatfield, D., McCullough, L., Frantz, S.H.B., & Krieger, K. (2010). Do we know when our clients get worse? An investigation of therapists' ability to detect negative client change. *Clinical Psychology & Psychotherapy, 17*, 25–32

How to spot deterioration

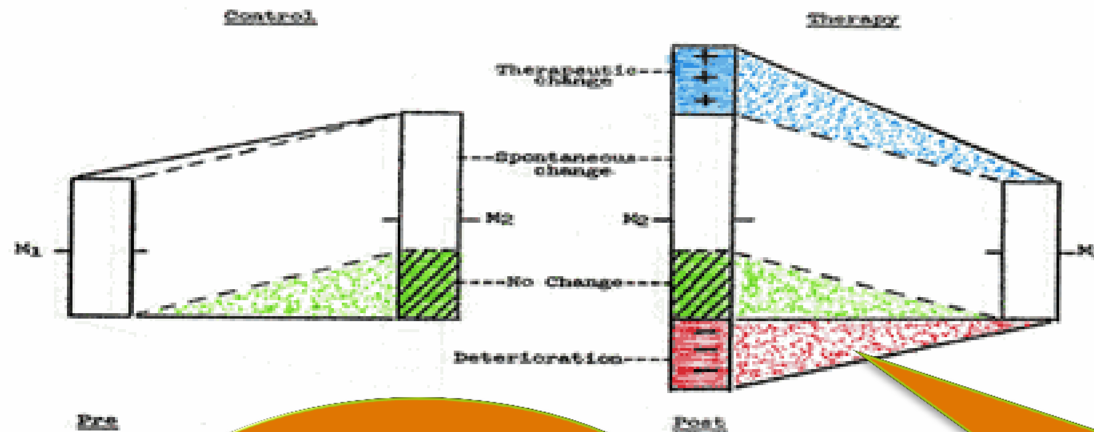
Use quantitative and qualitative methods

* Symptom change
  * Clinician observed
  * Rating scale
  * Therapist inquiry
  * Other person's report
* Alliance worsens
* Treatment goal failure
* Appointments missed
* Decreased motivation to change

Use measures systematically

Avoid positive bias

The Deterioration Effect – Bergin (1966)



Need to know HOW harm is caused and avoid harmful practices

Even empirically supported therapies may harm some people

Mechanisms of harm

- Cambridge-Somerville Delinquency ... study
  - At 30 years after the start of treatment, those who were in the treatment group were more likely to have been convicted of serious crimes, died on average ... younger, and have received a psychiatr...

Deviance training?

Repeated attendance at summer camp associated with recidivism

Mechanisms of harm

* Critical Incident Stress Debriefing
  * Higher PTSD and anxiety
  * Even though people find it helpful
* Scared Straight
  * Increased odds of offending
* Drug Abuse Education
  * Can make drug abuse more likely

Premature termination of exposure to anxiety-provoking stimuli?

See prisoners as role models?

Normalise the use of some substances?

Mechanisms of h

Deviance training?

Har d mainly in adult who were treated in groups

* A review of systematic reviews recidivism) of delinquency preve
* 8 of 15 reviews of treatments rec
  * Scared Straight
  * Second Respond
  * Boot Ca
  * Drug
  * Pris
  * Co r domestic violence
  * An ools
  * Cus ns

Structured programmes give better outcomes – may prevent the interactions that lead to deviancy transmission

Welsh, When crime prevention harms: A review of systematic *of Experimental Criminology, 10*, 245-266.

Mechanisms of harm

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untreated
* Effect more pronounced in t
compared with secure settin

Non-completers may be high risk and would do worse a

OR does non-completion make people worse?

Dropout → feel unable to change
Removal → increase anti-authority attitudes
Interruption → problems raised but not solved

Mechanisms of harm

* Need more theoretically-driven investigations into mechanisms by which harm may arise

The phrase that is guaranteed to wake up an audience: "And in conclusion."

In conclusion…

Research Implications

* Good clinical care should not be neglected when evaluating specific interventions
* Need clear theoretically-based hypotheses about the expected positive and potentially adverse interim and final outcomes in psychotherapy
* These should be stated in the protocol along with how and when they are to be assessed
* Findings should be reported in the final report

Clinical Implications

* Patients should be informed about the nature of the therapy before it starts.
* Information should include potential positive and negative outcomes so that patients can weigh up the costs relative to benefits
* Treatments and therapists need to be competent to meet the needs of ethnic and sexual minorities

Clinical Implications

* Therapists need to avoid looking <u>only</u> for positive outcomes
* They should specify theoretically-based expected positive and negative outcomes, at what stages of therapy they are expected, and how long the effects are likely to last
* These positive and negative outcomes should be monitored systematically and frequently over the course of therapy
  * Quantitative and qualitative measures
* Also, ask people what else is happening in their lives – life events may be more responsible for changes than therapy

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