The Elephant on the Couch:
Should we take ‘harm’ from psychological interventions more seriously?

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The PEPs Trial – a Unique Outcome?

- Psycho-Education and social Problem Solving (PEPS) is a RCT for personality disordered adults in the community, funded by HTA.

- Recruitment to the trial was stopped in Nov. 2012 by the Trial Steering Committee because of an excess number of inpatient hospitalisations (a pre-defined adverse event in the protocol) in the active arm of the trial.

- Was stopping recruitment to the trial reasonable? Was it unique? How are adverse events recorded in clinical trials using psychological interventions?
Reasons why we ought to take ‘harm’ seriously when using psychological treatments

• In principle, any potent treatment may result in an individual getting worse as better. As psychological treatments become more efficacious, there is a parallel need to consider the ‘Harm’ they may produce (Parry, 2000)

• Nonetheless, there is evidence that the evaluation of ‘psychotherapy’ is ‘…historically weighted to the benefit side of the equation’ (Berk & Parker, 2009).

• There is therefore an ‘assumption…that psychotherapy is only talking…no possible harm could ensue.’ (Nutt & Sharpe, 2009).
A Typology of Harm

Definition

Harm
1. Sustained deterioration
2. Caused by the psychological intervention

Measured by

Subjective Report
a) Effect on Self
   1) Increase in symptoms or development of new symptoms
   2) Behavioural deterioration
   3) Increased dependency
   4) Other

b) Effect on Others
   1) Spouse/Partner
   2) Family
   3) Friends
   4) Other

Objective Report
1) Increase in Mortality
2) Increase in Re-offending etc.

Produced by
1) Inappropriate treatment
2) Inappropriate application of an appropriate treatment
3) Patient characteristics e.g. Alexithymia etc.

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## A list of potentially ‘harmful’ psychological interventions (after Lilienfeld, 2007)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Incident Stress Debriefing</td>
<td>Post Traumatic Stress Disorder</td>
</tr>
<tr>
<td>Bereavement Grief Counseling</td>
<td>Depressive symptoms</td>
</tr>
<tr>
<td>DARE Programme</td>
<td>Increased intake of alcohol</td>
</tr>
<tr>
<td>Recovered memory techniques</td>
<td>Production of false memories</td>
</tr>
<tr>
<td>Boot camp interventions</td>
<td>Exacerbation of conduct problems</td>
</tr>
<tr>
<td>Scared Straight</td>
<td>Increase in offending</td>
</tr>
<tr>
<td>Etc.</td>
<td></td>
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</tbody>
</table>

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Scared Straight is a low cost and easy to implement strategy to prevent juvenile delinquency.

It involves visits to prisons where the juveniles interact with adult inmates in ‘rap’ sessions and their behaviour is challenged.
Initial evaluation claimed a 80-90% success rate and sparked a television documentary together with a roll out through 30 jurisdictions in the US and further afield.

More thorough evaluations, however, showed the reverse and that the intervention increased the rate of offending by between 1.6 to 1.7 to 1. (Petrosino et al. 2013).
### Harm from Scared Straight (Petrosino 2013)

Recidivism Rate Lower in the Control Group

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#### Review: 'Scared Straight' and other juvenile awareness programs for preventing juvenile delinquency

Comparison: 1 Intervention versus control, crime outcome

Outcome: 2 Postintervention - group recidivism rates - official measures only (random-effects)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Treatment n/N</th>
<th>Control n/N</th>
<th>Odds Ratio M-H, Random, 95% CI</th>
<th>Weight</th>
<th>Odds Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yarborough 1979</td>
<td>27/137</td>
<td>17/90</td>
<td></td>
<td>21.6%</td>
<td>1.05 [0.54, 2.07]</td>
</tr>
<tr>
<td>Orchowski 1981</td>
<td>16/39</td>
<td>16/41</td>
<td></td>
<td>15.2%</td>
<td>1.09 [0.44, 2.66]</td>
</tr>
<tr>
<td>Vreeland 1981</td>
<td>14/39</td>
<td>11/40</td>
<td></td>
<td>13.9%</td>
<td>1.48 [0.57, 3.83]</td>
</tr>
<tr>
<td>GERP&amp;DC 1979</td>
<td>16/94</td>
<td>8/67</td>
<td></td>
<td>14.7%</td>
<td>1.51 [0.61, 3.77]</td>
</tr>
<tr>
<td>Lewis 1983</td>
<td>43/53</td>
<td>37/55</td>
<td></td>
<td>15.3%</td>
<td>2.09 [0.86, 5.09]</td>
</tr>
<tr>
<td>Michigan D.O.C. 1967</td>
<td>12/28</td>
<td>5/30</td>
<td></td>
<td>9.5%</td>
<td>3.75 [1.11, 12.67]</td>
</tr>
<tr>
<td>Finckenauer 1982</td>
<td>19/46</td>
<td>4/35</td>
<td></td>
<td>9.8%</td>
<td>5.45 [1.65, 18.02]</td>
</tr>
</tbody>
</table>

**Total (95% CI):**

- **436**
- **358**
- **100.0%**
- **1.72 [1.13, 2.62]**

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Test for overall effect: Z = 2.55 (P = 0.011)

Test for subgroup differences: Not applicable

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‘If one argued that a two hour visit cannot perform the miracle of deterring socially unacceptable behavior (see Cook & Spirrison, 1992), it can also be argued that it was extremely simplistic to assert that a two hour visit can perform the miracle of causing socially unacceptable behavior (Holley and Brewster 1996).’
Richard Clarke Cabot
1868-1939
Professor of Clinical Medicine & Professor of Social Ethics,
Harvard University
Cambridge Somerville Youth Study

- Instigated on the belief that delinquency was caused by poor home circumstances, this intervention sought to remedy these deficiencies by providing ‘…support, friendship and timely guidance’ by a trained counsellor.

- Each boy (age range 6-13 years with a median of 10.5) was matched with another across a range of variables to ensure that they (and their families) were similar and then randomised to the treatment or control condition.

- The counsellors provided guidance to the boys and parents, referred to specialists as appropriate, encouraged the boys to join community groups, to get jobs etc. This trial continued for 5 years.
The trial ended in 1945 and it appeared that many of the boys in the treatment group had improved in their level of adjustment. They and their parents also reported being satisfied with the intervention.

However, compared to their controls, there was no difference in their outcome across a series of measures, so it was proposed to conduct a longer term follow-up as treatment effects were expected to appear as the youths matured.
The Long Term Effect of CSYT

- Hence, Joan McCord conducted a 30 year follow-up between 1975-1981 achieving a 98% ascertainment.

- Among the 253 pairs, there was no difference in their outcome in 150.

- But in the 103 where there was a paired difference, those in the treatment group were more likely (a) to have died prematurely, (b) to suffer from major mental disorder and (c) to have committed two or more crimes (d) show signs of alcoholism (f) to have lower levels of occupational attainment etc, (i.e. to have fared worse!) (McCord, 1978).
Was treatment harmful?

- Adverse effects increased with increased intensity and duration of treatment (i.e. it reflected a dose response relationship).

- Adverse effects occurred only among boys whose families had cooperated with the programme.

- Nonetheless, the explanation for ‘why’ this harm occurred has proved to be elusive. ‘The evidence simply is not in.’
Let me emphasise again the fact that the Cambridge-Somerville Youth Study was *effective*. The intervention had lasting effects. *These effects were not beneficial.* The important legacy of the program, however, is its contribution to the science of prevention.’

(McCord, 2003)

i.e. CSYS did have an impact – although not in the expected direction
These findings should cause Forensic Psychiatrists to pause and think as…

• Many of our psychological interventions are provided in a group context (e.g. SOTP).

• Many of those provided with treatment have high levels of deviancy.

• There is evidence that one of the mechanisms leading to a poor outcome is as a result of ‘deviancy training’. (Dishion & Dodge, 2005)
What is the status of harm in modern Clinical Trials?
Evidence that harm from interventions is not taken sufficiently seriously in Clinical Trials.

- Understandably, trials focus on efficacy rather than on harm (Ioannidis et al. 2004)

- Harm is more likely to be reported in pharmacological than in non-pharmacological treatment (Ethgen et al 2005).

- This reporting is especially poor in mental health where ‘… very few drug trials and practically none of the nondrug trials have adequate reporting of clinical adverse events…’ (Papanikololou et al. 2004).
Has the Situation Improved?

• Psychological interventions for Personality Disorder … Adverse events mentioned in only 1 of 38 trials and reported in none. (Gibbon et al, 2010; Stoffers et al. 2012).

• In HTA funded trials, adverse events now mentioned in 55% of the protocols of trials of psychological interventions but in none in the reports from completed trials. (Duggan et al in prep).
What does this absence of harm in reports mean?

• That no Harm occurred?

• That Harm occurred but it was neither recognised nor recorded?

• That Harm occurred and was recognised and/or recorded but not reported?
But, it is not all gloom!

- Over 50 years ago, Alan Bergin (1966) wrote about ‘The Deterioration Effect’ in Psychotherapy, encouraging trialists to consider the harm of the intervention in addition to its benefits.

- He observed that the variance in the active intervention was generally greater than the no treatment control.

- This implied that, when there was no difference in the mean effect in the outcome between the two groups, this increase in the variance in the active treatment condition implied that while many more were profiting from the intervention than in the no treatment control, these were being compensated for by those who had deteriorated or harmed;
The Deterioration Effect – Bergin (1966)

Figure 1
The Deterioration Effect: Schematic Representation of Pre- and Posttest Distributions of Criterion Scores in Psychotherapy-Outcome Studies

Note. Plus signs indicate greater improvement, whereas minus signs indicate greater deterioration. $M_1 =$ pretest mean criterion score; $M_2 =$ posttest mean criterion score. From “Some Implications of Psychotherapy for Therapeutic Practice,” by A. Bergin, 1966, Journal of Abnormal Psychology, 71, p. 238. Copyright 1966 by the American Psychological Association.
Investigating ‘Harm’ – Our Great Opportunity!

• While clinical trials are difficult to carry out, their design provides the most valid estimate of harmful effects.

• Hence, trialists ought to look for such adverse effects and report on the full range of scores by individual – not just the mean effect.

• At an individual level, inspection of the outliers in the fourth quartile might identify those who are being harmed by the intervention.

• This identification is only the first step, what is then required is a mechanism to explain that effect.

• Successful application of this process would, not only lead to the avoidance of harm but identify which psychological intervention ‘...works best for whom’.
Is “Harm” the Elephant on the Couch?

_Psychiatrie_
References

Thank You

&

Any Questions?