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Gaps in measures of adverse outcomes relating to psychological interventions

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In 1966, Dr Allen Bergin first published evidence that some individuals become significantly worse after psychotherapy (Bergin, 1966). Now, more than five decades later, there is wider acceptance that, as with any powerful treatment, psychological therapies may have negative as well as positive effects. Beneficently intended treatments may prove to be inherently harmful; grief counseling for normal bereavement is one such example (Lilienfeld, 2007). It is important to know this as early as possible and stop such interventions in such circumstances. Most adverse

effects, however, will fall into four main categories, including 1. temporary discomfort or distress, 2. longer term adverse effects, or even actual harm, but effects which are generally outweighed by benefits, 3. harms which do not outweigh benefits or 4. perverse outcomes or damage which follow from the intervention being curtailed. It is essential to recognise these possibilities and to accumulate evidence on their nature and extent, not only to maximise benefit over harm, but also to enable people considering treatment engagement to be able to make informed choices about whether to have the treatment at all, or, if having it, how to minimise risks. Our concern is that the knowledge gap in this area is still much wider than it should be, and that this could be remedied.

It is estimated that some negative effects occur in between 5 and 20% of psychotherapy patients, varying with type of therapy (Linden & Schermuly-Haupt, 2014). Despite these concerns, it has been estimated that among 132 randomised controlled trials of psychotherapies published in the calendar year 2010, just 21% included some kind of monitoring for harms (Jonsson, Alaie, Parling & Arnberg, 2014). Among all 82 studies of psychotherapy funded by the UK's National Institute for Health Research (NIHR) between 1995 and 2013, none mentioned occurrence of an adverse event other than failure to respond, and none mentioned adverse side effects; their protocols referred to measurement of 'serious adverse events', borrowed from drug trials, which refer only to death or near death experiences (Duggan, Parry, McMurrin, Davidson, & Dennis, 2014).

Failure to address adverse outcomes in the forensic mental health literature more specifically

A number of reviews have been published since 2013 on the effects of non-pharmacological treatments for mentally ill individuals in forensic psychiatric or criminal justice settings (Barnao & Ward, 2015; Rampling et al., 2016; Ross, Quayle, Newman, & Tansey, 2013; Sturgeon, Tyler, & Gannon, 2017), but, again, none refers to adverse effects other than failure to respond. An ongoing review of psychological treatments for forensic mental health patients has been auditing how potentially adverse effects of treatment have been measured in included studies (McIntosh, Janes, O'Rourke, Thomson, in preparation). In all 62 of these studies, whether interventions were designed to reduce offending behaviour or psychiatric symptoms, only three studies (5%) were explicit about using any method for monitoring any possible unwanted effects. Two studies acknowledged the potentially negative effect of the interventions (group psychoeducation and CBT for schizophrenia, respectively) on mood and report choosing mood state measures in the study assessment batteries for this reason (Aho-Mustonen, Tiihonen, Repo-Tiihonen, Ryyänen, Miettinen, & Rätty, 2011; Williams, Ferrito, & Tapp, 2014). In the third study, a randomised controlled trial (RCT) of schema therapy compared to treatment as usual (TAU) for offender-patients with personality disorder, the authors defined and measured negative outcomes as therapy drop-out, transfer to another hospital due to poor treatment response and criminal recidivism (Bernstein, Nijman, Karos, Keulen-de Vos, de Vogel, & Lucker, 2012). None of the studies in the review, including the 11 RCTs, referred explicitly to adverse events or a safety monitoring plan during the conduct of the evaluation. There was, however, evidence that data collected systematically for other purposes, for example to explain sources of missing data, could also serve as indicators of adverse effects. Fourteen studies (23%) in the review reported that some participants experienced a deterioration in mental state or had new symptoms emerge during treatment, and fifteen studies (24%) noted some deterioration on outcome measures

during study involvement. Twenty-six studies (42%) reported participant drop-out but provided inadequate information about reasons for drop-out, so it is possible some of these participants discontinued treatment due to perceived adverse effects. Thus, although not explicitly presenting adverse effects of the interventions, these studies offer a partial view of such effects. Of course, researchers cannot report everything in the limited space of a journal article, so non-reporting in this context is not proof that they did not consider adverse outcomes, but it is of concern.

Planned measurements of adverse effects might, however, add crucial information about whether they are likely to be transient or longer lasting and how they might be minimised. If harmful effects of treatments are not systematically examined, the research is potentially unethical.

Further, perhaps particularly among offender-patients, harms may not be confined to the participant. Learning points from this review informed the design of a safety monitoring plan in an ongoing feasibility RCT of a group psychological intervention delivered in Scottish forensic mental health services (McIntosh, Slessor, O'Rourke, & Thomson, 2018).

Is it better to half-treat or not treat at all?

Most studies evaluating treatments do at least report drop-out rates, and some distinguish between participant-initiated drop-out and treatment failures for other reasons. Could failing to complete treatment itself be harmful? If so, would it be safer to avoid attempting treatment at all?

There is good evidence that failure to complete an offender programme may yield worse outcomes for non-completers than offenders of comparable risk who never started the programme, both in terms of re-offending (McMurrin & Theodosi, 2007) and psychological traits such as impulsivity (Palmer & Humphries, 2016). Those who fail to complete programmes may, however, be those at greatest risk of adverse outcomes anyway (Lilienfeld, 2007; Schneibel

et al, 2017). One methodological issue is that there is little consensus on what constitutes ‘treatment completion’. Some might argue that treatment has been completed when a mutual therapist-patient agreed end-point is reached, but others that it is when every planned session is attended, or where an arbitrary minimum proportion of sessions are attended (Cullen, Soria, Clarke, Dean, & Fahy, 2011; Long, Fulton, Dolley, & Hollin, 2011). To some extent, this depends on the nature of the programme in that the session content of psychoeducational approaches may require completion of all sessions for maximum skills acquisition, whereas the effectiveness of more psychotherapeutic approaches may vary according to an individual’s speed of progress.

In the Groups for Alcohol-misusing Short-term Prisoners (GASP) randomized controlled trial (RCT) of a 9-session group-based intervention drawing on motivational interviewing and skills development compared to TAU for drug/alcohol abusing short-term prisoners, treatment completion was defined as missing no more than two consecutive sessions and where catch-up work was completed. The GASP trial featured an embedded process evaluation which sought to uncover reasons behind treatment non-completion (Moriarty, McNamara, Robling, Kissell, Playle, & Taylor, 2015; Moore et al., 2015). ‘Prison systems problems’ made up the main reason for session loss (about one third of a possible 1071 sessions), and early release accounted for a further 10%; 16% of sessions were lost as men disengaged or had personal problems. The number of sessions attended was, however, unrelated to change in the primary outcome, which was locus of control. Further, treatment non-completion was not associated with negative secondary outcomes, such as mental state deterioration. Moderator analyses found that prisoners whose non-completion was due to personal choice had reported less hazardous drinking

behaviour before treatment than either prisoners who completed treatment or those whose non-completion was primarily due to prison-problems. This appears consistent with previous evidence (McMurrin & McCulloch, 2007) that prisoners who initiated treatment drop-out may do so because they felt the treatment was less relevant to their current concerns, and not in this case due to experienced harm from treatment.

Improving adverse outcome and side effect reporting – drawing from theory behind the intervention and making balanced calculations?

In both treatment evaluations and clinical practice, theory drives the interventions and the treatment targets. Why, then, should theory not similarly drive considerations of harmful effects?

In the Psychoeducation and Problem-Solving (PEPS) intervention for adults with personality disorder trial (McMurrin et al., 2017), four individual sessions of psychoeducation and 12 group sessions of problem-solving were compared with TAU in people with personality disorder living in the community. Psychoeducation is a mainstream intervention for personality disorder, and a pilot study had been completed showing that PEPS was likely to be beneficial (McMurrin, Egan, & Duggan, 2001). Despite these important points, recruitment to the PEPS trial was halted when the Data Monitoring and Ethics Committee observed that more adverse events had occurred in the PEPS arm than in the TAU arm. In total, there were 117 adverse events among 60 participants in the treatment arm and 76 adverse events from 39 participants in the TAU arm. This difference between the trial arms was not statistically significant. The PEPS arm included 4 deaths (2 due to natural causes and 2 due to suicide, one of which occurred before the start of treatment) and the TAU arm none; most adverse effects were of severe substance use and self-harm. There may have been a bias in adverse event recording in that there were more follow-up

days in the PEPS arm, and also, compared with those in TAU who had less overall contact with the PEPS staff, those in the PEPS arm may have felt more able to tell the PEPS therapists and researchers about their difficulties. A major difficulty existed in establishing whether or not adverse outcomes were actually related to the treatment. This led the team to propose that, in future, protocols for treatment and evaluation should state *in advance* what adverse effects might theoretically be attributable to the intervention and if these are likely to be short term effects due to temporary destabilization or serious adverse effects that suggest that treatment should stop.

Moving forward

There is currently no consensus definition of adverse effects of psychological treatment in forensic population, although we set out the four main areas for concern at the outset. There is still much to learn about why adverse outcomes occur, whether they are temporary or longer-term responses to therapy, and whether patient, therapist, or organization-level factors may be associated with their occurrence, or even explain them. These unanswered questions cannot paralyze necessary progress (Parry, Crawford, & Duggan, 2016), and among the tasks facing researchers is greater rigour in understanding the theoretical basis for any intervention, which may help point to its risks as well as benefits. It seems logical, for example, to anticipate that interventions which require revisiting of painful realities of which the participant has previously been avoidant will be distressing, at least temporarily. The important questions are about how much distress and for how long may be acceptable in such circumstances and whether there is a threshold that may put the person at risk of becoming worse, maybe including becoming suicidal.

Addressing potential harm from treatment is not just an obligation for trialists running large, well-controlled RCTs with the ability to unpick causality, nor even researchers more generally. Every clinician and researcher involved in the delivery or evaluation of a psychological treatment has opportunities to advance this work:

- Selected outcome measures should include reliable and valid scales which allow measurement of key features in a range above and below the likely entry score of participants. Thus, deterioration may be observed as readily as improvement.
- Theory of outcomes should include prediction of potential harms as well as benefits, so that if adverse changes are observed, it is more possible to disentangle those which are attributable to the intervention from co-incidental harms.
- In addition, researchers should consider using a self-report measure (Rozenal, Kottorp, Boettcher, Andersson, & Carlbring, 2016) or structured checklist (Linden, 2013) designed to measure adverse treatment effects considered to be possible on grounds of the theoretical basis of the intervention.

It goes almost without saying that appropriate procedures should be in place to manage adverse events optimally, but here we are principally concerned with filling the gap in measurement. Finally, we acknowledge that so long as journals continue to publish RCTs and other treatment evaluation studies which disregard potential harmful effects of treatment, researchers may have little incentive to change. The primary responsibility for ensuring attention to possible side effects of psychological treatments lies with researchers, but funding bodies, research ethics committees, peer-reviewers and journal editors may also have important roles in play in raising the accepted standard for good research practice.

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