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Editorial

Iatrogenic harm from psychological therapies – time to move on†

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Summary
The problem of adverse effects of psychotherapy has been recognised for decades, yet research on causes and prevention of harm has failed to progress. There is confusion between different definitions and a lack of systematic recording and reporting. A new framework for moving this field forward is proposed.

Declaration of interest
G.P. was chief investigator of an NIMH-funded project that led to the development of the Supporting Safe Therapy information resource (www.supportingsafetherapy.org).

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Evidence has accumulated for the effectiveness of psychological therapies in the treatment of a wide range of mental disorders, as well as adjunctive treatment in physical conditions, to the point where national clinical guidelines routinely include recommendations for their application. In the UK a National Health Service programme to Improve Access to Psychological Therapies (IAPT) is well established. This is a far cry from 30 years ago when sceptical editorials attributed psychotherapy results to placebo effects.[1] As a range of evidence-based psychological therapies have become routine in mainstream health services, interest has grown in the potential for these treatments to cause harm; in the same way that effective medical treatments carry risks and toxicity, it is becoming clear that psychological treatments cannot be at once psychoactive and harmless.

Patient safety has not been a priority for psychological therapy researchers. Despite repeated attention to this issue over five decades and recently renewed interest, comparison of discussions from the 1960s to the 2000s shows the field has failed to progress significantly.[2,3] Part of the difficulty in accumulating knowledge is the plethora of different terms used in research reports, with confusion between them and no systematic way to describe adverse effects of treatment. In a recent scoping review as part of a research programme on this topic, we needed over 14 search terms to address the issue, including negative effects, adverse effects, adverse events, harm, symptom exacerbation, treatment failure, clinical deterioration, negative outcome, harmful effects, patient safety, negative therapeutic reaction, negative results. Failure to agree the most appropriate terms and definitions to describe harm associated with psychological treatments may help explain the striking disparity between the large amount of testimony on the internet from patients describing their experience of harm from therapy, compared with little or no reference to the risk of harm in the major textbooks in the field.[4]

These definitional problems make it difficult to compare results of different studies and have limited progress in our understanding of what leads to harm and what might be done to prevent it. In this editorial we highlight deficiencies in the way that research is currently reported, provide definitions for types of harm associated with psychological therapies that would improve the way results of future studies are presented, and summarise the implications for research and practice.

Causes of negative effects and harm in psychological therapies

An important feature of all psychological treatments, in contrast to pharmacological ones, is the extent to which the effectiveness of the therapy crucially depends on the skills of the therapist to co-create the 'active ingredients' with each patient anew. In this respect, psychological therapies are more analogous to surgery than to pharmacological treatment. There is the added complexity that the relationship between the therapist and the patient is itself an 'active ingredient' that is an important predictor of outcome, and although enhanced by good technique[5] it goes beyond technical competence. There is no guarantee that the therapy delivered is what was specified in the 'prescription' or what was investigated in a randomised trial. For example, National Institute for Health and Care Excellence (NICE) guidelines on the treatment of depression draw evidence from randomised trials of therapies delivered by well-trained professionals, which ranged from 12 to 30 sessions,[6] but the median treatment length in IAPT services in England is 5, often delivered by underqualified staff.[7]

There are many posited risk factors for negative outcomes and possible mechanisms for harmful therapy. These include:

(a) damaging interactions between therapist and patient and unresolved ruptures in the therapeutic alliance;

(b) therapist factors: for example, using an inappropriate therapeutic method or errors in delivering a recommended therapy; lack of skill in noticing and repairing ruptures in the therapeutic alliance;

(c) patient factors that increase the risk of iatrogenesis: for example, activation of attachment in people with reduced mentalisation such as those with borderline personality disorder;[8]

(d) poor fit between therapist and patient: for example, a generally skilful therapist who is unable to work with grief for personal reasons;

†See pp. 208–209 and 260–265, this issue.

(e) risks attached to specific interventions: for example, the possibility of maladaptive learning in group-based treatment;

(f) organisational systems: for example, suboptimal provision due to large case-loads and organisational pressure to take on patients beyond one's competence.

It is difficult to report the proportion of therapy patients who experience negative results from therapy as there are few systematic studies of prevalence. The estimate of 5% is typical.[9] This is consistent with results from a survey of psychological therapy service users in England, where 1 in 20 respondents reported that they had experienced lasting bad effects from therapy.[10] Negative therapeutic results may be higher for children and young people.[11]

Failure to record and report

Reports of clinical trials of psychological therapies are far less likely to mention adverse effects than pharmacological trials;[12] a review of mental health trials[13] found only 28 of an eligible 132 trials (21%) showed any indication that adverse events had been monitored, and even fewer were reported. Duggan *et al*[14] examined both the protocols and the final reports, whether published or unpublished, from trials commissioned by the Health Technology Assessment programme of the UK National Institute of Health Research. They confirmed that, despite the mandatory paragraph on adverse events required for obtaining ethical approval, only a small proportion of trials monitored them. They found such comments as 'There is no evidence that CBT [cognitive–behavioural therapy] is harmful. IAPT therapists are experienced in conducting risk assessment' and 'No adverse events or serious adverse events will be recorded or reported in this study'. However, there was evidence that more recently commissioned trials were improving in this respect. The patient experience of an adverse therapy process or outcome is rarely recorded.

Three ways to move the field forward

We have three recommendations to address these problems. First, greater standardisation of terms is required. As a starting point, we suggest the following definitions for a range of adverse effects of therapy.

(a) Adverse events refer to significant episodes during or shortly after treatment (e.g. suicide, suicide attempts, mental health-related hospital admissions), which if related to or directly caused by treatment amount to harm or severe harm.

(b) Clinically significant deterioration refers to a worsened mental state after therapy is complete, which can include the emergence of new symptoms. It is often a psychometric criterion from patient-reported or clinician-assessed outcome measures. In this context, harm refers to sustained, statistically reliable deterioration having been caused by therapy but consensus on what is a statistically reliable and clinically significant degree of deterioration has not yet emerged.

(c) Finally, but crucially, the patient may have a very negative experience of therapy, with lasting bad effects, despite this not being picked up either in adverse event monitoring or observed clinical deterioration. This could be described as patient-experienced harm. Those close to the patient can also experience harm from the treatment.

From this, we recommend that ideally all these aspects of potential harm should be monitored and reported in research trials. Adverse events should plausibly be related to the effect of the intervention on the population being studied and should be specified in the protocol and reported routinely in published reports. Those specified should be specific to the population in the trial, for example suicide, increase in self-harm, psychotic relapse (not simply hospital admissions), increased use of alcohol/drugs, relapse of eating disorders and emergence of new symptoms: a checklist for unwanted events and adverse treatment reactions specific to psychological therapies may be useful in this regard.[15] Rates of clinical deterioration in treatment and control groups should be shown, in addition to the usual group mean differences. This is vital for meta-analysis, since the numbers in any individual trial are too small and confidence intervals too large to draw robust conclusions. Finally, the view of trial participants on any experience of therapy harm is an important but often missing perspective. By using a mixed-methods approach, researchers and practitioners can throw light on whether observed deterioration is or is not related to the therapy process.

We also recommend that routine monitoring of adverse events, patient deterioration and drop-out are included in clinical audit of psychological therapy services, with follow-up investigation of patient-experienced harm where these exceed normative limits for the case mix. Lambert has demonstrated a method of reducing treatment failure through case monitoring and feedback.[16] These three simple steps would, in our view, move this field forward considerably, so that we will not be rehashing the same concerns 50 years from now.

We also require methods to test putative mechanisms. These could include task analysis of therapy process, intensive single case replications and multilevel modelling in large samples to understand the interaction between factors. Such research can provide a basis for developing and testing interventions aimed at reducing harm and help us better understand how to improve the mental health of those who have experienced such harms. It is also needed to generate data that will provide patients and clinicians with more reliable information to make treatment choices. At present, patients are often asked to provide consent to psychological treatment without any discussion of potential harms associated with these interventions. Although negative effects associated with psychological therapies are far less common than positive ones, the process of informed consent requires some consideration of both.

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psychiatry in the movies

The Babadook

Jayesh Busgeet

'Ba-ba-ba . . . dook! Dook! DOOOOOKH!'

The Babadook, debut of writer-director Jennifer Kent, was released in late 2014. It paints a horror story where the source of the fear has a particular familiarity. *The Babadook* portrays itself as a dark children's story but in true Grimm's fairy tale fashion with a Jungian twist that creates more terror than the brothers Grimm could ever imagine. With the predictable paranormal shocks and demonic activity that the movie industry continues to churn out, *The Babadook* is a dark gem that not only has you biting your nails but draws you into its emotional engagement with its characters.

It tells a fairy tale of a single mother, Amelia, starring fantastic Essie Davis who is haunted by the violent death of her husband and who battles with her son's terror of a monster known only as the Babadook. Kent's writing throughout expertly reminds her viewers of *We Need to Talk about Kevin* and *The Omen* that similarly enters the taboo realm of paedophobia, which employs a disturbing tale with the fear of parenting as a psychological vessel.

Our journey begins with a conflicted Amelia and her struggle in a mundane life. We can sense her exhaustion and burden at taking care of her son, Samuel, who presents at the least with difficult behavioural problems. Her husband has died many years ago while driving her to hospital pregnant with Sam – a painful birthday reminder that repeatedly forces her not to celebrate this impending occasion. Thus, we are introduced to Amelia – a once happily married and successful children's writer now driven down by grief, pain and something darker lurking underneath.

When Samuel asks his mother to read a mysterious black book, *Mister Babadook*, that scares us more than the *The Evil Dead's Necronomicon*, she thinks nothing much of it until the story's darker features insidiously unfold. Amelia and Sam's terror soon leads to the destruction of the book only for it to eerily show up again on her doorstep with frightening charcoal crafted pictures akin to nightmarish Tim Burton animations.

Amelia, who began this journey with our sympathy, slowly begins to claw at our fear as an intense anger grows towards her son while being trapped in a maelstrom of grief and guilt. As the malevolent entity attempts to scare with a 'BANG!', Freud's *Return of the Repressed* is whispering behind our ear urging us to dive deeper underneath Amelia's hidden iceberg. We are rewarded with the image of the Babadook but the true terror at the heart of this tale is its grim reality and not the entity with the top hat and Freddy Krueger's claws.

Kent's unique Grimm-Jungian fairy tale continues to shock throughout and ends with a final peculiar scene that appears to resonate well with Carl Jung's quote: 'To confront a person with his own Shadow is to show him his own light'. *The Babadook*'s sheer symbolism and metaphor turns a clichéd mainstream horror into a masterful terror that will linger long after you cuddle your children into bed, for 'if it's in a word, or it's in a look, you can't get rid of the Babadook . . . '

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