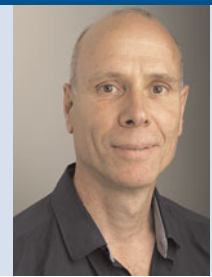


Editorial

Recommendations for monitoring and reporting harm in mindfulness for psychosis research

Lyn Ellett and Paul Chadwick

**Summary**

There is increasing interest in potential harmful effects of mindfulness-based interventions. In relation to psychosis, inconsistency and shortcomings in how harm is monitored and reported are holding back our understanding. We offer eight recommendations to help build a firmer evidence base on potential harm in mindfulness for psychosis.

Keywords

Mindfulness; psychosis; harm; schizophrenia; adverse events.

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One of the most significant recent developments in the field of psychotherapy has been the emergence of mindfulness-based interventions (MBIs). In relation to psychosis, MBIs were slow to develop, in large part because of concern that people with psychosis are particularly vulnerable to harmful effects arising from mindfulness practice.¹

Operationalising harm in psychotherapy research

Harm in psychotherapy research has traditionally been defined as the occurrence, following an intervention, of a deterioration in symptoms or functioning that is sustained, is likely to have been caused by the intervention and is more severe than it would have been had the individual not received the intervention.² This definition highlights two immediate complexities in defining harm in psychotherapy. First, a proportion of people with mental health conditions will experience a deterioration in symptoms with or without an intervention, so it is important to establish a baseline rate of deterioration. Randomised controlled trials (RCTs) are particularly useful in this regard, as the inclusion of a control arm provides a valid point of comparison from within the same clinical setting and time frame. Second, a deterioration means more than simply a change in score – to determine the clinical significance of a change in symptoms or functioning it is helpful to know the minimal clinically important difference (MCID) for any given outcome measure.

A second approach to operationalising harm that is commonly applied in RCTs is to report the occurrence of both serious adverse events (SAEs), defined by the World Health Organization as life-threatening or fatal occurrences, and adverse events (AEs), defined as untoward events experienced by study participants. SAEs and AEs may or may not be caused by the intervention. In a review of the available research on harm in mindfulness-based psychotherapies across a range of conditions (but not psychosis), Baer et al report that AEs or SAEs occur in 0–10.6% of research participants, and are no more common in mindfulness-based psychotherapies than in control arms of trials.²

A third approach to operationalising harm has been to consider indirect or proxy indices of harm, such as study drop-out rate – the argument being that drop-out rates would be higher in psychotherapies experienced as unsafe by patients.

Is mindfulness for psychosis harmful?

The literature on mindfulness-based therapies for psychosis is growing fast. An evidence base comprising more than 20 RCTs (see Jensen et al for the most recent meta-analysis³), alongside numerous uncontrolled studies, evidences a range of clinical benefits of mindfulness for psychosis, including reduced negative symptoms and levels of depression, and enhanced psychological quality of life.³ Although these randomised studies do not suggest that mindfulness for psychosis is harmful, a closer look at how harm is operationalised, monitored and reported in mindfulness for psychosis research reveals some critical shortcomings that make it impossible to provide a data-driven answer to the question ‘Is mindfulness for psychosis harmful?’ We offer below eight recommendations (summarised in the Appendix) on how harm should be operationalised, monitored and reported, to strengthen the evidence base on potential harm in mindfulness for psychosis research.

Recommendations for reporting of harm

Study design

First, although uncontrolled research studies were pivotal to the development of mindfulness for psychosis, priority should be given to findings from RCTs when drawing generalisable conclusions about harm. The discipline in RCTs of applying a common set of study inclusion and exclusion criteria within a standardised recruitment protocol, combined with the inclusion of a control arm and random treatment allocation, provides a valid point of comparison from which to understand observed levels of harm in those receiving mindfulness for psychosis. Although uncontrolled studies will always be useful in flagging important potential issues of risk and harm, and in ongoing therapy development, they do not provide a solid basis for drawing firm conclusions about harm in mindfulness for psychosis.

Serious adverse events

Second, there are inconsistencies in reporting of SAEs. All future studies should state explicitly the number of SAEs by study arm;

if there were none, then this should be stated explicitly. This is already a recommendation in reporting of trials, but it is not always applied in the MBI for psychosis literature. Also, there is some confusion about what constitutes an SAE in mindfulness for psychosis research. For example, in one study a participant death was not reported as an SAE because it was attributed to natural causes. Crucially, an SAE is defined by the untoward event itself and not by degree of imputed causal connection with study participation. Although it is informative to include indications of likely degree of connection between a life-threatening or fatal occurrence and study participation, it always remains an SAE and should be reported as such.

Hospital admissions

Third, there is lack of clarity around reporting of hospital admission. As with other SAEs, it is sometimes simply not reported on – does this mean that it was robustly monitored and did not occur, or that it was not monitored? Harm in psychotherapy is such an important issue that clarity is essential. Data should minimally include the number of participants in each arm who were admitted to hospital – if there were none in a study arm, then this should be stated explicitly. If admissions were not monitored, then this should be stated explicitly as a study limitation. Where applicable and possible, data on hospital admissions might be supplemented by data on usage of crisis or home treatment teams.

Further inconsistency can arise in trials of MBIs for psychosis that use the hospital admission or readmission rate as an outcome measure. Authors typically report admission rates as clinical outcomes but not also as adverse events. This substantially distorts reported rates of adverse events in mindfulness research. Selecting an adverse event as a study outcome does not obviate the need also to report it as an adverse event. Hospital admissions should always be reported as adverse events, as is done in non-psychotherapy research.

Adverse events

Fourth, although real-world practical constraints mean that it is not possible to monitor all potential adverse events, what is practicable is for researchers to follow Jacobsen et al⁴ in stating clearly in their trial protocol those adverse events that were deemed particularly relevant to the trial, specifying how these were monitored (e.g. review of case notes) and giving detailed descriptions of any such untoward events that did occur.

Side-effects

Fifth, researchers are encouraged to consider using a standardised patient-reported side-effects questionnaire in trials of MBIs, as is done in trials of medication. None of the trials included in the most recent meta-analysis³ of MBIs for psychosis did so. Side-effects are distinct from adverse events and will occur in all psychotherapies. Recording subjective side-effects will broaden understanding of potential harm in MBIs for psychosis.

Symptom deterioration

Sixth, although studies increasingly seek to contextualise benefits of MBIs by reporting the number of participants who showed a clinically important improvement on measures of psychological functioning, it is rare for studies to report how many participants experienced a clinically important deterioration. None of the randomised trials of MBIs for psychosis included in the most recent meta-analysis³ reported data across all study arms on clinically important deterioration on the primary measure of psychological functioning – and we have found only one RCT published since

then that included data on clinically important deterioration on the primary outcome measure across all study arms.⁵ Whenever possible, clinically important symptom deterioration by study arm should be reported in all future studies.

Drop out


Seventh, drop out occurs for many reasons but it can be a useful indirect index of harm. CONSORT diagrams show study drop out – the number of participants who did not provide post-intervention or follow-up data. However, a participant who ceased attending therapy yet still provided post-intervention assessment data would not be recorded as a study ‘drop out’. It would be useful for future studies to report not only study drop-out rates (including, where known, the reason), but also therapy non-completion rates as determined against a preset number of sessions (e.g. attending at least 50% of sessions).

Public and patient involvement

Finally, it will be important in future studies to ensure meaningful public and patient involvement (PPI) in research assessing harm. Studies are encouraged to state explicitly if and how PPI input contributed to specific decision-making on how harm was operationalised and monitored.

Conclusions

There is a pressing need to improve monitoring and reporting of harm in mindfulness for psychosis research – indeed, in the wider literature on MBIs – in order to develop a fuller understanding of both beneficial and harmful effects.

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First received 13 Jan 2021, final revision 8 Jun 2021, accepted 14 Jun 2021

Author contributions

Both authors contributed equally to all aspects of the manuscript. Both authors have approved the final version to be published and agree to be accountable for the accuracy and integrity of the work.

Funding

This research received no specific grant from any funding agency, commercial or not-for-profit sectors.

Declaration of interest

None.

Appendix

Criteria and recommendations

- (a) Study design:
 - (i) data from randomised controlled trials should be prioritised when drawing generalisable conclusions about harm in mindfulness for psychosis research.
- (b) Serious adverse events:
 - (i) all life-threatening and fatal occurrences should be reported as serious adverse events (SAEs), regardless of degree of causal connection with study participation

- (ii) if there were no SAEs, this should be clearly stated
- (iii) if SAEs were not monitored, this should be listed as a study limitation.
- (c) Hospital admissions:
 - (i) hospital admissions should always be reported as adverse events, even when admission is a study outcome
 - (ii) if there were none, this should be clearly stated
 - (iii) should be supplemented with data on usage of crisis services if possible
 - (iv) if admissions were not monitored, this should be listed as a study limitation.
- (d) Adverse events:
 - (i) list which instances of less serious adverse events were monitored
 - (ii) list how they were monitored (e.g. case note review).
 - (iii) provide detailed descriptions of any adverse events that occur.
- (e) Side-effects:
 - (i) include standardised patient-reported measure of side-effects.
- (f) Symptom deterioration:
 - (i) all instances of clinically meaningful deterioration in symptoms or psychological functioning should be reported.
- (g) Drop out:
 - (i) report study drop out, and reason for drop out (including direct or indirect link to harm), by treatment arm
 - (ii) report separately drop out and non-completion of therapy.
- (h) Public and patient involvement (PPI):
 - (i) ensure meaningful PPI in decision-making about how harm is operationalised and monitored.

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Psychiatry in history

The Külliye of Sultan Bayezid II

Aykan Pulular  and Raymond Levy

In medieval times under the Ottoman Empire the mentally ill were treated with dignity and humanity. Restraints were minimal and might consist of a thin silver cord. One of the examples left today is in the Turkish city of Edirne, second capital of the Ottoman Empire and principal centre of Thrace, where there stands the Külliye ('Complex') of Sultan Bayezid II. Built in 1488, during a period when the mentally ill were generally treated badly, the hospital within the Külliye used an approach that was ahead of its time. There were three parts to treatment: music, the sound of running water and a variety of different scents. This approach was widespread throughout the empire in what were known as *bimaristan* or *darussyifa*. Examples can still be seen in Damascus, Aleppo and Cairo as well as in Bursa and Istanbul. The complex comprised a medical school (madrasah), a hospital (*darussyifa*) for both physical disorders and the insane, an imaret (the social aid unit that served free food to the poor and the staff in the Külliye), a mosque, guesthouses, a *muvaqqithane* (a unit that was concerned with the calendar and the time of the day), Turkish baths, a watermill and a bridge. Today only some parts of the complex survive: the small mosque, the madrasah and the *darussyifa*.

There were three sections in the *darussyifa*. The first was for out-patient services, the second was for the staff and the third served as an in-patient ward. Its architectural design was based on a central system positioned so as to use relatively few staff. This section consisted of a big hall covered by a high dome, with six winter rooms and four summer rooms around it and a stage for the musicians. In the middle of the hall a fountain ran water over the sloping floor to a gutter designed to collect the overflow. It also provided a source for washing the patients. The tranquillising sound of the running water from the fountain, combined with the scents of various herbs and flowers such as jasmine, carnation, tulip and hyacinth, was used to alleviate patients' anxiety. The musicians played three times a week, and different modes of Turkish classical music were used for each illness. The dome of the hall provided a particularly good acoustic.

Although we do not know how successful these methods were, we can assume that they were at least relatively humane and ahead of their time. The Külliye in Edirne was fully restored and reopened its doors to visitors as a museum in 1997. It was awarded the Council of Europe Museum Prize for the year 2004.

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The British Journal of Psychiatry (2021)
219, 631. doi: 10.1192/bjp.2021.108