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Dear Editor,

Addressing risk of bias in service-collected data

In their letter *Overcoming the scourge of missing data in psychotherapy trials*, Clark and colleagues raise the issue of missing data and recommend using routinely collected session-by-session data, as is available in the English National Health Service (NHS) Talking Therapies (previously, Improving Access to Psychological Therapies) program. Whilst, in principle, we agree with this aspiration, such a method generates specific threats to data integrity.

Our trial protocol[1], published prior to data collection completion, proposed using multiple imputation rather than replacing missing data with service-collected data. Our reasons were twofold. First, as is typical in NHS Talking Therapies, service-collected data were typically obtained by unblinded practitioners who treated trial participants and routinely discussed scores on measures with participants as part of the intervention. Data collected by unblinded assessors and intervention providers inflates risk of bias[2] and using unblinded assessors counters both Cochrane[3] and CONSORT[4] clinical trial criteria. Second, service-collected data was obtained in different ways in different services, and the timing of the final session varied considerably. Hence, the combination of increased risk of bias and method collection variance presents challenges to adopting service-collected data as a method to address missing data.

However, we had ethical approval to access service-collected session-by-session data during the intervention. When missing Time 1 data (16-week primary end-point) was replaced by the most recently available service-collected data, missing data was only 3.4%. An exploratory sensitivity analysis using this revised dataset confirmed the superiority of practitioner-supported MBCT-SH over practitioner-supported CBT-SH on the primary outcome (PHQ-9) at 16 weeks postrandomization with a between-group difference of −1.4 points (95%CI, −2.4 to −0.3; P = .009; d = −0.34). This result is almost identical to that arising from the primary, pre-registered analysis yielding a between-group difference at 16 weeks postrandomization of −1.5 points in favor of practitioner-supported MBCT-SH (95%CI, −2.6 to −0.4; P = .009; d = −0.36)[5]. Whilst we agree that trial data may be more likely to be missing for people who fared poorly, our re-analysis suggests that this risk is not different between trial arms.

Although we would welcome efforts to reduce missing data, as we discuss in our article[5], we suggest that session-by-session service-collected data in services such as NHS Talking Therapies serves an important but different purpose to data collected in clinical trials. The purpose of session-by-session data in NHS Talking Therapies is to monitor progress and guide and adjust intervention planning[6], and thereby serves a crucial role in improving recovery rates. Collecting these data with high

completion rates and using them to improve recovery rates has been an extraordinary achievement in NHS Talking Therapies. However, data quality does not meet the blinding standards required of clinical trials[3,4] where it is essential that data are collected in ways that minimize risk of bias[3,4] so that the most accurate estimates of effects can be determined. For these reasons, we advocate considerable caution in adopting service-collected data as a strategy to replace missing psychotherapy trial data.

(489 words)

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References

1. Strauss C, Arbon A, Barkham M, et al. Low-Intensity Guided Help through Mindfulness (LIGHTMIND): Study protocol for a randomised controlled trial comparing supported mindfulness-based cognitive therapy self-help to supported cognitive behavioural therapy self-help for adults experiencing depression. *Trials*. 2020;21(1):374. doi:10.1186/s13063-020-04322-1

2. Hróbjartsson A, Thomsen ASS, Emanuelsson F, et al. Observer bias in randomized clinical trials with measurement scale outcomes: a systematic review of trials with both blinded and nonblinded assessors. *CMAJ*. 2013;185(4):E201-E211. doi:10.1503/CMAJ.120744

3. Higgins J, Thomas J, Chandler J, et al., eds. *Cochrane Handbook for Systematic Reviews of Interventions Version 6.3 (Updated February 2022). Available from Www.Training.Cochrane.Org/Handbook.* Cochrane; 2022.

4. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:869. doi:10.1136/BMJ.C869

5. Strauss C, Bibby-Jones AM, Fergal Jones ;, et al. Clinical Effectiveness and Cost-Effectiveness of Supported Mindfulness-Based Cognitive Therapy Self-help Compared With Supported Cognitive Behavioral Therapy Self-help for Adults Experiencing Depression: The Low-Intensity Guided Help Through Mindfulness (LIGHTMind) Randomized Clinical Trial. *JAMA Psychiatry*. Published online March 22, 2023. doi:10.1001/JAMAPSYCHIATRY.2023.0222

6. Lutz W, Schwartz B, Delgadillo J. Measurement-Based and Data-Informed Psychological Therapy. *https://doi.org/101146/annurev-clinpsy-071720-014821*. 2022;18:71-98. doi:10.1146/ANNUREV-CLINPSY-071720-014821