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Online supplement

Earlier this year, Clarke and colleagues published an admirable report of a randomised trial.[42] It evaluated cognitive analytic therapy (CAT) for personality disorder compared with treatment as usual. The study included 99 participants, and the report includes a compelling account of the intervention and its outcomes. This online supplement describes ways in which their article complies with CONSORT guidelines,[10] and we also use their article as an example to highlight details that are often absent in trial reports but improve the application and understanding of their results. Working with a group of stakeholders to develop CONSORT-SPI, we hope to reach a widespread consensus about how such information should be reported in the future.

Following current guidelines, Clarke and colleagues identify the study as a randomised trial in the title (Item 1a) and provide a structured summary of trial design, method, results and conclusions (Item 1b). Our review found that only 20% of trials in leading social and psychological journals were identified as randomised trials in the title, and Clarke *et al*'s report is more likely to be identified by reviewers and policy makers because it complies with this reporting standard.

The main text is also an example of good reporting overall. In the introduction, the authors provide the scientific background and study objectives (Item 2). The method section includes key features of design (Item 3), detailed eligibility criteria for participants (Item 4a), the location of the study (Item 4b) and staffing for the control group (Item 5). Following the CONSORT extension for non-pharmacological interventions,[18] the authors describe the intervention, including: format, staffing, intended duration, intended frequency and fidelity (using the Competence in CAT measure). In Clarke *et al*, Table 1 shows characteristics of each group (Item 15), the number of participants included in each analysis (Item 16) and results (Item 17). The authors also report sensitivity analyses and describe mechanisms of change (Item 18).

To include a study in a systematic review, it is necessary to assess its quality. This report includes most of the information required to complete the Cochrane Risk of Bias Tool or a similar measure (Table DS1). The authors describe the prespecified outcome measures (Item 6a), as well as the addition of two measures after randomisation (Item 6b). Randomisation (Item 8), allocation concealment (Item 9) and recruitment (Item 10) are all described well. It is clear that outcome assessors were unaware of treatment assignment (Item 11a), although the authors did not specifically describe the similarity of interventions (Item 11b).

Several aspects of the study could be reported more comprehensively to fully comply with existing guidelines. Although included in the text, the abstract does not include information about setting, masking procedures, numbers randomised and effect sizes, which are recommended in the CONSORT extension for abstracts.[37] The text includes details of trial registration (Item 23), but not the location of a full trial protocol (Item 24). The flow chart reports the number of participants assigned, receiving treatment and analysed for the primary outcome (Item 13a), but it does not include reasons for drop out (Item 13b).

In addition to areas covered in existing reporting guidelines, we believe the utility of this report would be improved by the inclusion of more information about key features of social and psychological interventions, areas that CONSORT-SPI will address. The report already includes a strong discussion section with details of methodological strengths and limitations (Item 20), generalisability (Item 21) and the relationship between this study and overall evidence in the area (Item 22). Given the complex nature of this intervention, it could also be useful to include further information about: the components of CAT and how they should be delivered, an explicit theory of change linking the mechanisms of the intervention to the targeted outcomes within this context, further details about the actual delivery and uptake of the intervention (for example individual tailoring, resources utilised, proscribed activities), and specific details about the delivery and uptake of interventions by participants in the control group. The authors reported that the trial occurred in a specialist personality disorder clinic in a public health setting in Dorset, UK, but the report does not describe the setting sufficiently for all readers to assess external validity of the trial; for example, a reader in another country or in the future might wonder about the nature and quality of the 'treatment as usual' in the control group. Although aspects of the recruitment process were reported, the actual period of recruitment and any incentives for participants were not described – these details might help readers understand the nature of this population. Furthermore, the article did not make any mention of relevant concurrent events, service environment characteristics or aspects of the delivering organisation that might influence interpretations of the study findings. These could include availability of alternative treatments outside the trial context, economic or policy changes that influence the quality of services, provider or participant preferences for different types of treatment or service, or compatibility of the clinic's organisation with the intervention.

Table DS1 Cochrane risk of bias table for Clarke *et al*'s study

Bias	Our judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'The random sequence was computer generated'
Allocation concealment (selection bias)	Low risk	'Treatment allocation concealment was achieved using a telephone-based system of randomisation, administered by the Dorset Research and Development Support Unit'
Masking (performance bias and detection bias)	Low risk for outcome assessment; high risk for participants and providers	'best endeavours were used to ensure that assessors were masked to treatment allocation (e.g. participants were asked not to mention any information that could allow assessors to guess their treatment condition)'
Incomplete outcome data (attrition bias)	High risk	20% or more attrition in each condition with no explanation as to why participants could not be followed up. Only included data from participants who provided it for pre and post
Selective reporting (reporting bias)	Low risk	All outcomes reported except post-intervention healthcare utilisation costs

We commend Clarke and colleagues for publishing an excellent report in a leading journal. Their work demonstrates that reports of social and psychological interventions can easily adhere to reporting standards in existing guidelines, and improved adherence to these standards could further improve the quality and utility of these reports. However, a report of a social or psychological intervention that fully adheres to the CONSORT Statement may still omit information that could help readers understand the internal and external validity of a study. A consensus process is needed to identify and to disseminate reporting standards for research in this field.

Additional reference

42 Clarke S, Thomas P, James K. Cognitive analytic therapy for personality disorder: randomised controlled trial. *Br J Psychiatry* 2013: **202**: 129–34.