

POSTER PRESENTATION

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P05.50. CONSORT extension for N-of-1 trials (CENT) guidelines

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Purpose

N-of-1 trials have been used in medicine to generate treatment information when evidence from randomized controlled trials (RCTs) is not available or applicable. N-of-1 study design maintains the methodological safeguards provided by RCTs (blinding, randomization and controls) yet avoids the disadvantages associated with large trials. A standardized method of reporting of N-of-1 trials, such as the Consolidated Standards of Reporting Trials (CONSORT), would greatly improve the quality and consistency of trial reports in this area. The objective of this study was to develop a CONSORT Extension for N-of-1 Trials (CENT).

Methods

Checklist items for the CENT guidelines were derived from three systematic reviews on N-of-1 conduct, analysis and meta-analysis. A structured process of obtaining information from a group of experts to refine and finalize the CENT guidelines was carried out. Two stages of questionnaires asked participants to rate the relative importance of suggested checklist items; the second questionnaire was refined based on feedback from the previous one. Participants included those known to have interests in either RCT reporting or N-of-1 methodology. Items included after the Delphi process were debated and finalized during an in-person meeting.

Results

There were 44 unique respondents between the two rounds of questionnaires. Based on questionnaire results, topics chosen for discussion at the in person meeting included: terminology (what is "N-of-1?"), randomization and blinding, research vs. clinical care, and analysis and meta-analysis. The CENT checklist was

refined and adapted to the format of the most recent CONSORT 2010 statement.

Conclusion

N-of-1 trials may promote an evidence-based approach to therapy so that families, health care providers and policy-makers can make informed choices, and are relevant to both conventional and complementary and alternative medicine. The CONSORT 'extension' will facilitate critical appraisal and interpretation of N-of-1 trials by providing authors with guidance on how to improve reporting.

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