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Assessing the reporting quality of adult neuro-oncology protocols, abstracts, and trials: Adherence to the SPIRIT and CONSORT statements

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Abstract

Background: Comprehensive and transparent reporting of clinical trial activity is important. The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 and Consolidated Standards of Reporting Trials (CONSORT) 2010 statements define the items to be reported in clinical trial protocols and randomized controlled trials, respectively. The aim of this methodological review was to assess the reporting quality of adult neuro-oncology trial protocols and trial result articles.

Methods: Adult primary and secondary brain tumor phase 3 trial protocols and result articles published after the introduction of the SPIRIT 2013 statement, were identified through searches of 4 electronic bibliographic databases. Following extraction of baseline demographic data, the reporting quality of independently included trial protocols and result articles was assessed against the SPIRIT and CONSORT statements respectively. The CONSORT-A checklist, an extension of the CONSORT 2010 statement, was used to specifically assess the abstract accompanying the trial results article. Percentage adherence (standard deviation [SD]) was calculated for each article.

Results: Seven trial protocols, and 36 trial result articles were included. Mean adherence of trial protocols to the SPIRIT statement was 79.4% (SD: 0.11). Mean adherence of trial abstracts to CONSORT-A was 75.3% (SD: 0.12) and trial result articles to CONSORT was 74.5% (SD: 0.10).

Conclusion: The reporting quality of adult neuro-oncology trial protocols and trial result articles requires improvement to ensure comprehensive and transparent communication of planned neuro-oncology clinical trials and results within the literature. Raising awareness by clinical triallists and implementing mandatory evidence of proof of adherence by journals should improve reporting quality.

Keywords: CONSORT; CONSORT-A; SPIRIT; clinical trial.

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