

Completeness of intervention trial protocols: a systematic survey

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Introduction: The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT1) 2013 guideline provides guidance to improve the quality of protocols. The aim of this study was to determine the completeness of randomised controlled trial protocols evaluating the efficacy or effectiveness of HIV prevention, treatment and care strategies using the SPIRIT 2013 checklist, and to identify factors associated with completeness of trial protocols.

Methods: We searched MEDLINE, EMBASE, LILACS, Africa-wide information (EBSCOhost), Web of Science, Clinicaltrials.gov and CENTRAL (Wiley Cochrane Library) for randomized controlled trial protocols in May and June 2018. We included protocols for interventions in the HIV prevention, treatment and care fields published between 2008 and 2018. Two individuals independently screened the titles and abstracts. The adapted SPIRIT checklist was pilot tested independently in duplicate on the first 4 (5%) protocols. The rest of the data was collected by a single individual and verified by second reviewer. Disagreements were resolved by consensus. We summarized categorical data using count (percent) and continuous variables using mean (standard deviation). Generalised estimation equations assuming a Poisson distribution were used to assess association of protocol factors with number of checklist items reported.

Results: Seventy-nine protocols met the eligibility criteria and were included in the analysis. A mean of 32 (SD= 5) of the possible 51 SPIRIT checklist items were reported in the protocols. Detailed methodological aspects relating to intervention allocation, blinding, data management, study monitoring and

dissemination policy information were often missing in the protocols. Intervention category, period of publication (before or after SPIRIT 2013 publication) and study setting were not significantly associated with protocol completeness.

Conclusion: There is need for improvement in the reporting of recommended SPIRIT 2013 checklist items in HIV intervention protocols. We recommend active implementation strategies of the SPIRIT guideline from publishing journals and HIV trialists to ensure more improvement in protocol quality.