

Lack of transparent reporting of trial monitoring approaches in randomised controlled trials: A systematic review of contemporary protocol papers

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Clinical Trials
1–12
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DOI: 10.1177/17407745221143449
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Abstract

Background: Monitoring is essential to ensure patient safety and data integrity in clinical trials as per Good Clinical Practice. The Standard Protocol Items: Recommendations for Interventional Trials Statement and its checklist guides authors to include monitoring in their protocols. We investigated how well monitoring was reported in published ‘protocol papers’ for contemporary randomised controlled trials.

Methods: A systematic search was conducted in PubMed to identify eligible protocol papers published in selected journals between 1 January 2020 and 31 May 2020. Protocol papers were classified by whether they reported monitoring and, if so, by the details of monitoring. Data were summarised descriptively.

Results: Of 811 protocol papers for randomised controlled trials, 386 (48%; 95% CI: 44%–51%) explicitly reported some monitoring information. Of these, 20% (77/386) reported monitoring information consistent with an on-site monitoring approach, and 39% (152/386) with central monitoring, 26% (101/386) with a mixed approach, while 14% (54/386) did not provide sufficient information to specify an approach. Only 8% (30/386) of randomised controlled trials reported complete details about all of scope, frequency and organisation of monitoring; frequency of monitoring was the least reported. However, 6% (25/386) of papers used the term ‘audit’ to describe ‘monitoring’.

Discussion: Monitoring information was reported in only approximately half of the protocol papers. Suboptimal reporting of monitoring hinders the clinical community from having the full information on which to judge the validity of a trial and jeopardises the value of protocol papers and the credibility of the trial itself. Greater efforts are needed to promote the transparent reporting of monitoring to journal editors and authors.

Keywords

Systematic review, trial monitoring, on-site monitoring, central monitoring, risk-based monitoring, reporting monitoring, protocol paper, randomised controlled trial

Background

Clinical trial monitoring¹ plays a vital role in ensuring participants’ well-being is protected, trial data are accurate and complete, and the conduct of the trial complies with the protocol, regulatory requirements and Good Clinical Practice (GCP) guidelines.² ‘Monitoring’ here refers to the methods used by a sponsor to oversee the conduct of, and reporting of data from, clinical trials, including the ‘review of site processes, procedures and records, and verification of the accuracy of data submitted to the sponsor’.³ In the past, clinical trials predominantly relied on on-site monitoring, in which trial monitors systematically and repeatedly visited sites

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 - The Rise of Digital Reading Methods Trial Papers
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 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
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 - Features to Look for in an Methods Trial Papers
 - User-Friendly Interface
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 - Interactive Elements Methods Trial Papers
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 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Methods Trial Papers
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 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
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 - Carving Out Dedicated Reading Time
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 - Utilizing eBooks for Skill Development

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