Publication bias - a cross-sectional study of randomised trials in sub-Saharan Africa: ongoing challenges of research waste

Ameer Hohlfeld[1,2], Tamara Kredo[1,2,3], Michael Clarke[1, 4]

1 Division of Epidemiology and Biostatistics, Faculty of Medicine and Health Sciences, Stellenbosch University, South Africa
2 Health Systems Research Unit, South African Medical Research Council, Cape Town, South Africa;
3 Division of Clinical Pharmacology, Department of Medicine and Division of Epidemiology and Biostatistics, Department of Global Health, Faculty of Medicine and Health Sciences, Stellenbosch University, South Africa
4 Northern Ireland Methodology Hub, Centre for Public Health, Queen's University Belfast, BT12 6BJ, United Kingdom

BACKGROUND

The World Health Organization recommends that results from randomized controlled trials (RCTs) should be published in peer-reviewed journals within 24 months of study completion. Globally, between 25% and 50% of trials remain unpublished, a phenomenon known as publication bias. This bias can lead to skewed evidence bases, potentially affecting healthcare decisions and policies. In Africa, there has been slow yet steady growth in the number of conducted RCTs. However, evidence on the extent of publication bias for these RCTs is lacking. Our objectives were to:

1. Assess the proportion of completed RCTs from Sub-Saharan Africa (SSA) that have been published
2. Determine the time from completion to publication for these trials

METHODS

We searched for completed and terminated RCTs from SSA registered in ClinicalTrials.gov and the Pan African Clinical Trials Registry (PACTR). The RCTs had to meet the following criteria: 1) at least one trial site in an SSA country, 2) either medical or non-medical related, 3) registered on or after 1 January 2010, 4) actual start date on or after 1 January 2010, 5) primary completion date before 1 January 2024, and 6) recruitment status recorded as terminated or completed. For all eligible RCTs, we searched online databases to determine whether they were published in a journal. We calculated the percentage of published RCTs and used Kaplan-Meier survival plots to analyze time to publication. Publication time was calculated as the number of months from the primary completion date until the publication date, using the online electronic publication date when available.

RESULTS

Our searches of ClinicalTrials.gov and PACTR yielded 7836 records, with 398 duplicates removed. After screening and applying eligibility criteria, we included 2799 RCTs in our final analysis (Figure 1). Of these, 1773 (63.3%) were published. Subgroup analysis revealed lower publication rates for PACTR-registered trials (44.1%) compared to ClinicalTrials.gov (67.7%), and for terminated trials (47.8%) versus completed trials (64.4%). Industry-funded trials had a higher publication rate (71.4%) than those with other funding sources (59.6%) (Table 1). The overall median time to publication from primary completion date was 34.5 months (95% CI: 33.0 to 36.1), with the cumulative percentage of published RCTs increasing rapidly in the first 50 months post-completion before leveling off around 75% (Figure 2).

CONCLUSIONS

Our study reveals that nearly two-thirds (63.3%) of RCTs conducted in SSA between 2010 and 2024 have been published. While this publication rate is encouraging, it also indicates that over one-third of trials remain unpublished, potentially leading to publication bias. The median time to publication of 34.5 months exceeds the WHO's recommended 24-month timeframe, suggesting delays in disseminating crucial research findings. These results highlight the need for targeted interventions to improve both the rate and speed of trial publication in SSA. Future research should investigate the factors contributing to publication delays and non-publication, as well as develop strategies to enhance the timely dissemination of trial results. Improving the visibility and accessibility of SSA trial outcomes could significantly contribute to evidence-based healthcare practices and policies in the region.

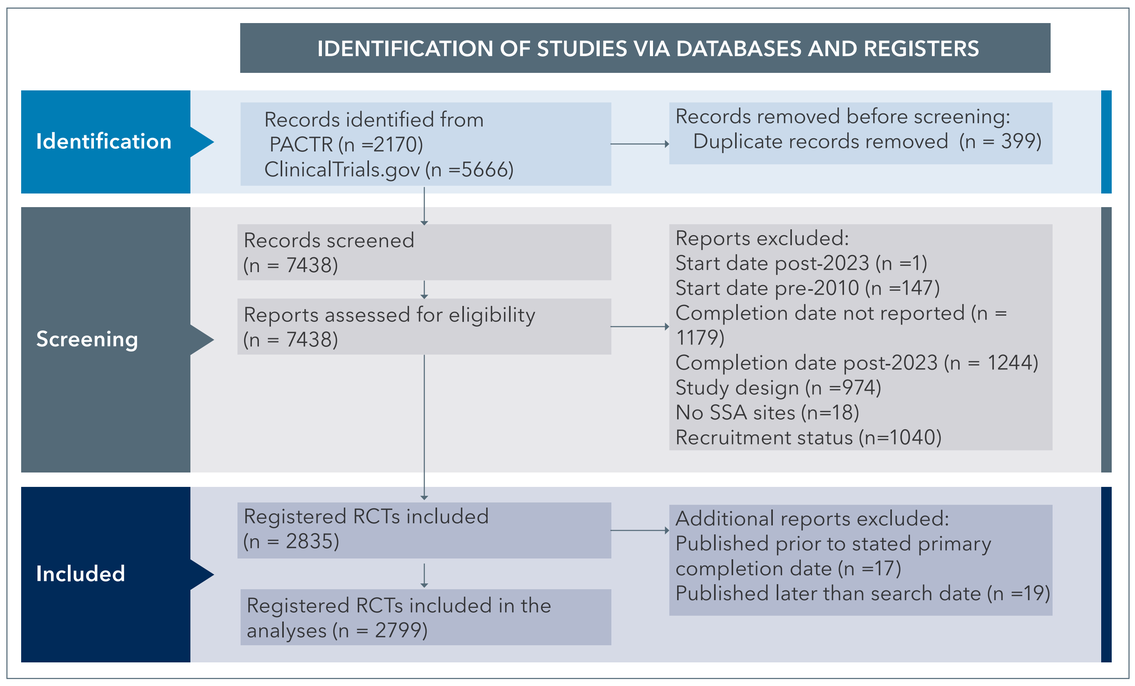

Figure 1. *Flow diagram from screening trial registrations*

Table 1. *Sub-group publishing percentages*

Characteristics		Number of RCTs (n= 2799)	Number of RCTs published (n=1773) (% of the total number of RCTs)
Trial Registry	PACTR	519*	229 (44.1)
	ClinicalTrials.gov	2296*	1555(67.7)
Recruitment status	Completed	2619	1687 (64.4)
	Terminated	180	86 (47.8)
Age	Adults	1710	1062 (62.1)
	Children	491	330 (67.2)
	Both adults and children	598	381 (63.7)
Funding source	Industry	889	635 (71.4)
	Other	1910	1138 (59.6)
Number of SSA sites	Single	2591	1619 (62.5)
	Multiple	208	154 (74.0)
*We added the 16 RCTs registered in PACTR and ClinicalTrials.gov			

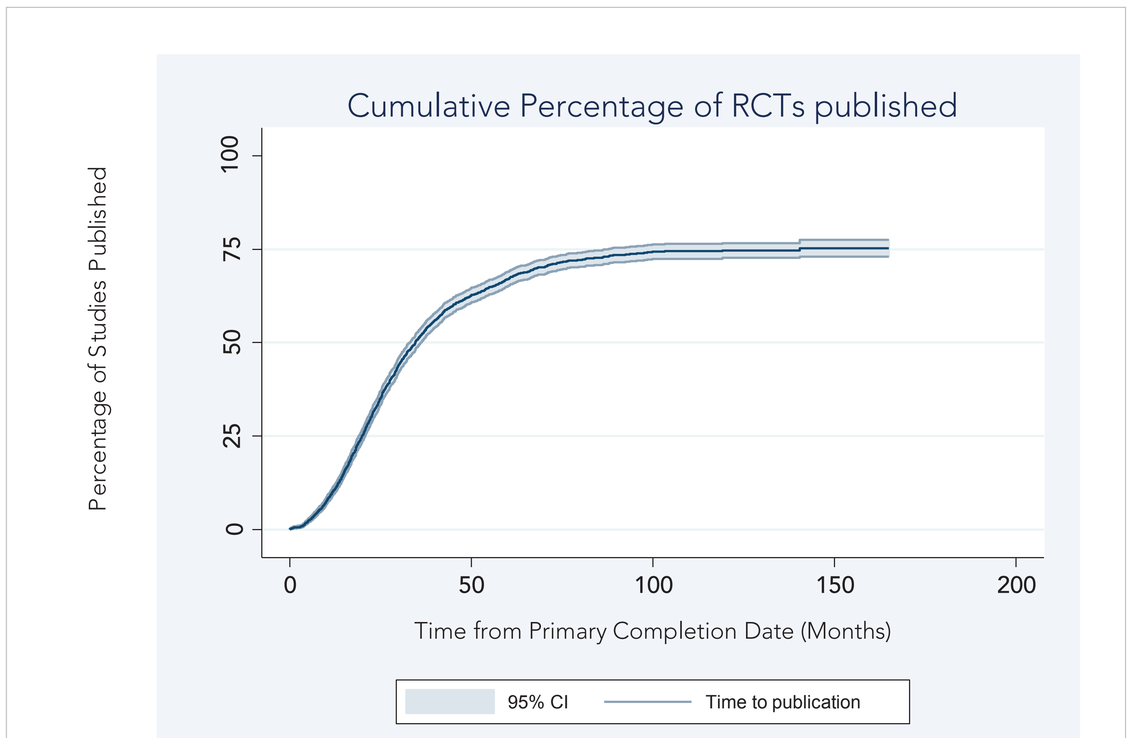

Figure 2. *Overall median time to publication of results in a journal*