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Considerations and dilemmas in preparing a randomized population health intervention trial: lessons from a South African-Canadian partnership to improve HIV and tuberculosis prevention and care for health workers

CITATION

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ABSTRACT

Background: Community-based cluster-randomised controlled trials (RCTs) are increasingly being conducted to address pressing global health concerns. Preparations for clinical trials are well-described, as are the steps for multi-component health service trials. However, guidance is lacking for addressing the ethical and logistic challenges in (cluster) RCTs of population health interventions in low- and middle-income countries.

Objective: We aimed to identify the factors that population health researchers must explicitly consider when planning RCTs within North–South partnerships.

Design: We reviewed our experiences and identified key ethical and logistic issues encountered during the pre-trial phase of a recently implemented RCT. This trial aimed to improve tuberculosis (TB) and Human Immunodeficiency Virus (HIV) prevention and care for health workers by enhancing workplace assessment capability, addressing concerns about confidentiality and stigma, and providing onsite counseling, testing, and treatment. An iterative framework was used to synthesize this analysis with lessons taken from other studies.

Results: The checklist of critical factors was grouped into eight categories: 1) Building trust and shared ownership; 2) Conducting feasibility studies throughout the process; 3) Building capacity; 4) Creating an appropriate information system; 5) Conducting pilot studies; 6) Securing stakeholder support, with a view to scale-up; 7) Continuously refining methodological rigor; and 8) Explicitly addressing all ethical issues both at the start and continuously as they arise.

Conclusion: Researchers should allow for the significant investment of time and resources required for successful implementation of population health RCTs within North-South collaborations, recognise the iterative nature of the process, and be prepared to revise protocols as challenges emerge.