Title: Overcoming obstacles to implementation of an interventional clinical trial on chronic psychotic disorders in Tanzania

Authors:
Martha Sajatovic[1], Tasiana Njau[2], Sylvia Kaaya[2], Jennifer B. Levin[1], Carol Blixen[1], Catherine Kahabuka[3], Hongyan Liu[1], Kristin Cassidy[1], Jessie Mbwambo[2]

Affiliations:
[1] Case Western Reserve University School of Medicine and University Hospitals Cleveland Medical Center, Cleveland, Ohio, U.S.A

[2] Muhimbili University of Health and Allied Sciences and Muhimbili National Hospital in Dar es Salaam, Tanzania

[3] CSK Research Solutions, Dar es Salaam, Tanzania

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Abstract:
Methodological question: What are optimal methods to overcome obstacles to the implementation of an interventional clinical trial targeting patients with chronic psychotic disorders in Sub-Saharan Africa (SSA)?

Introduction: Chronic psychotic disorders (CPDs) such as schizophrenia occur world-wide and cause significant burden, reduced quality of life, functional impairment and premature mortality due to suicide and other causes. Stigma and persistent disability, which usually begin early in life, profoundly and negatively impact people with CPD as well as their families and communities. Lower and middle income countries, including nations in SSA experience disproportionate burden due to poor adherence with evidence-based medication treatments, pervasive stigma, and lack of workforce capacity. In spite of the growing burden caused by CPD in SSA, there are numerous obstacles to research implementation and very few completed prospective clinical trials that can inform care.

Methods: This ongoing project is using a multi-stage process to develop and test a person-centered CPD care approach that will be practical and effective in Tanzania, generalizable to other countries in SSA, and develop research capacity for future efforts in clinical trials. The study team includes investigators from Muhimbili University of Health and Allied Sciences and Muhimbili National Hospital in Dar es Salaam, Tanzania, and from Case Western Reserve University (CWRU), Ohio, USA, and builds upon a successful behavioral + medication approach for high-risk individuals with CPD developed at CWRU.

Results: Steps in the 3-phase/3-aim project are: 1) A mixed-methods (quantitative + qualitative) needs assessment regarding barriers and facilitators to CPD care in Tanzania; 2) Refinement of a brief, customized adherence enhancement approach (CAE) to improve adherence and mental health outcomes in Tanzanians with CPD, and 3.) Establishment of a clinical trials infrastructure, adequately trained staff, and data tools/procedures preparatory to implementation of a randomized controlled trial (RCT) using the adapted CAE approach combined with long-acting injectable antipsychotic medication (LAI) in Tanzanians with CPD.

The Phase 1/Aim 1, mixed-methods analysis involves 100 individuals with CPD to better understand antipsychotic adherence barriers and attitudes. Phase 1 methods include evaluation of common reasons for non-adherence, as well as stakeholder input regarding preferred approaches for treatment and adherence promotion. In Phase 2/Aim 2, CAE is being culturally and linguistically adapted for the Tanzanian setting. In Phase 3/Aim 3 appropriate outcome measures will be selected, staff will be trained in study and measure implementation, and the intervention will be finalized for delivery. Finally, the adapted CAE approach combined with LAI will be evaluated in a 6-month prospective clinical trial format.

Conclusions: Taken together, this ongoing project is targeting common obstacles to clinical trials implementation in SSA, and will set the stage for a future large-scale RCT that has substantial potential for positive public health impact should preliminary methods and outcomes prove promising.