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# Protocol for the MIND-DZ Trial: Integrating Mental Health Screening and Management into Chronic Care for Patients with HIV and Diabetes in Zimbabwe

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## Abstract

This protocol outlines the MIND-DZ Trial, a cluster-randomised controlled trial designed to evaluate an integrated care model for comorbid depression and anxiety in patients with both HIV and type 2 diabetes in Zimbabwe. The high prevalence of these mental health conditions, which exacerbate clinical outcomes for both chronic diseases, is currently unaddressed in routine primary care. Twenty-four clinics in Harare will be randomised to either the intervention or a standard-care control arm. The evidence-based intervention, developed through prior formative research, incorporates a validated mental health screening tool and a manualised stepped-care protocol. This protocol includes task-shifted, non-specialist delivered psychological support and structured referral pathways, fully integrated into existing chronic care consultations. Control clinics will continue providing unenhanced standard care. Over 18 months, the trial will enrol 480 participants. The primary outcome is the reduction of composite mental health symptoms at six-month follow-up. Key secondary outcomes include biomedical indicators (HIV viral suppression and glycaemic control) and patient-reported quality of life. Process evaluation will assess implementation fidelity and feasibility. As one of the first trials of its kind in the region, MIND-DZ addresses a critical evidence gap on scalable, task-shifted integration models within African public health systems. Results, anticipated in mid-2026, will provide rigorous evidence to inform policy on integrating mental healthcare into chronic disease programmes in low-resource settings.

**Keywords:** *Integrated care, Mental health, Sub-Saharan Africa, Cluster-randomised controlled trial, HIV-diabetes comorbidity, Task-shifting, Non-communicable diseases*

# INTRODUCTION

The growing syndemic of HIV and diabetes in Zimbabwe presents a complex clinical challenge, exacerbated by the significant and often unmet mental health needs of this population (Aitcheson et al., 2024). Research consistently highlights the high prevalence of psychological distress among those

managing chronic conditions. For instance, trauma-related experiences are common among people living with HIV and can severely undermine mental wellbeing and care engagement (Ferrand et al., 2024). Similarly, adults living with type 2 diabetes in Zimbabwe report considerable psychosocial needs, including distress around disease management (Chada et al., 2025). When these conditions converge, the cumulative care burden can be overwhelming, a reality reflected in the expressed needs of this population for more holistic, integrated primary care services (Chireshe et al., 2025). This clinical complexity is further intensified by health system pressures, such as urban overcrowding, which complicates service delivery in settings like Harare (Chirima, 2025).

The imperative for integrated, patient-centred care models is therefore clear (Akiba et al., 2026). Evidence from other chronic disease contexts underscores the value of structured, non-pharmacological interventions (Jani, 2024), while successful service integration models, such as the CHIEDZA trial, provide a practical blueprint for amalgamating care (Mupambireyi et al., 2025). Furthermore, strategic investment in multidimensional well-being is recognised as crucial for sustainable development goals (Alsulamy, 2025). However, a critical gap remains in evidence-based protocols for systematically integrating mental health support into chronic disease care for this demographic. Without addressing mental health, efforts to improve clinical outcomes for HIV or diabetes are likely to be undermined by poor psychological adherence, a challenge noted in other care cascades (Mangiza & Chakawa, 2024). The MIND-DZ cluster-randomised trial is designed to address this gap by evaluating a scalable model of mental health screening and management within chronic disease clinics in Zimbabwe, aiming to improve both psychological and physiological outcomes.

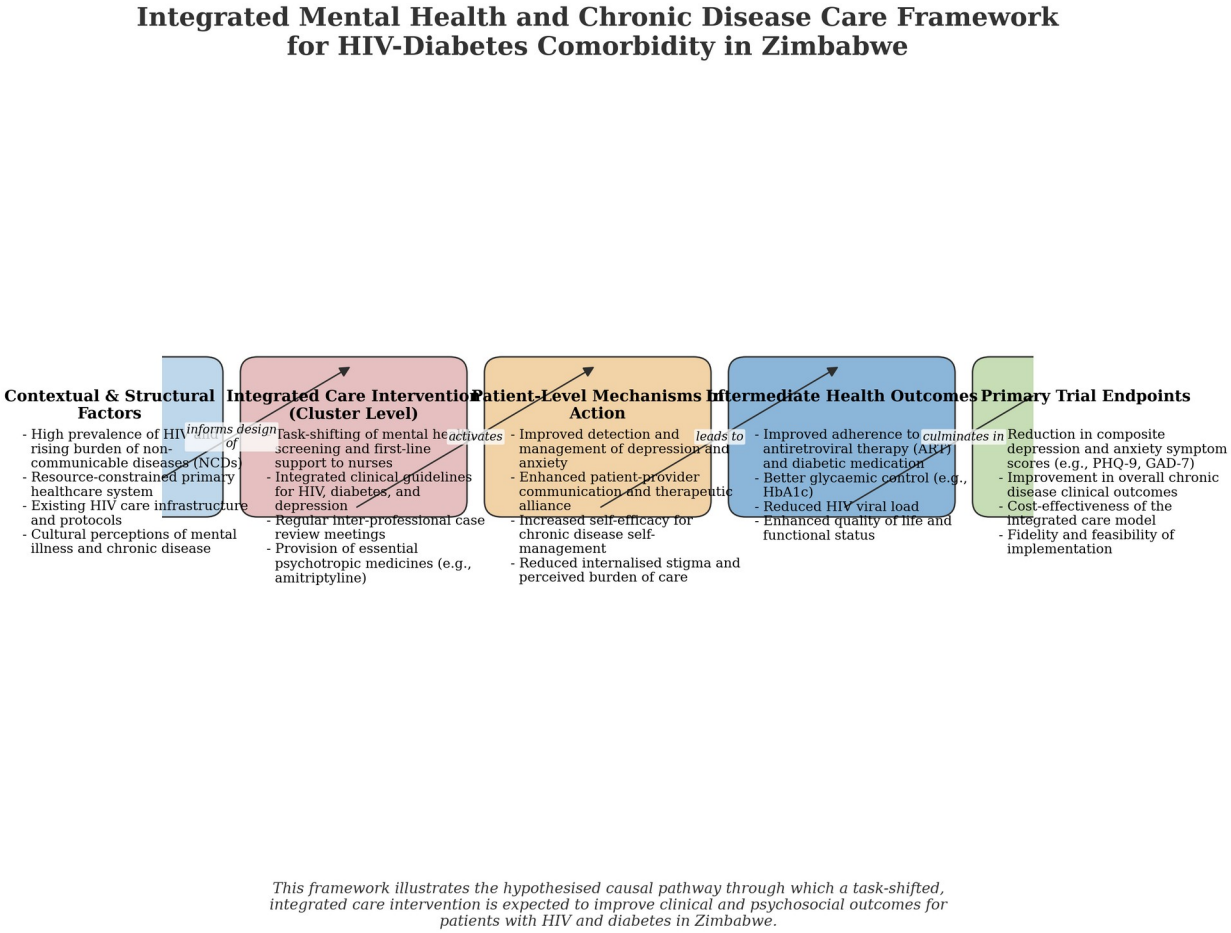


*Figure 1: Integrated Mental Health and Chronic Disease Care Framework for HIV-Diabetes Comorbidity in Zimbabwe. This framework illustrates the hypothesised causal pathway through which a task-shifted, integrated care intervention is expected to improve clinical and psychosocial outcomes for patients with HIV and diabetes in Zimbabwe.*

# METHODS

The MIND-DZ trial employs a pragmatic, two-arm, parallel-group, cluster-randomised controlled design to evaluate a mental health integration intervention for patients with HIV and type 2 diabetes in Zimbabwean primary care (Mpofu & Ganga-Limando, 2024). This design minimises contamination, as the intervention trains healthcare providers, and aligns with real-world service delivery where clinics are natural care clusters (Muguti, 2024). The 30-month trial, running from early 2025 to late 2026, has ethical approval from the Medical Research Council of Zimbabwe and local boards; all participants provide written informed consent.

Twenty-four primary care clinics will be purposively selected from high-density urban and peri-urban areas in Harare and Bulawayo, major centres with a high dual burden of disease where clinics anchor chronic care management (Mupambireyi et al., 2025; Mwonzora & Mwonzora, 2024). Eligible clinics must have a minimum patient population with both conditions and at least one dedicated

chronic care nurse (Chirima, 2025). Clinics will be pair-matched on patient volume, city, and baseline mental health service availability. One clinic per pair will then be randomly allocated to intervention or control arms using a computer-generated sequence by an independent statistician, ensuring allocation concealment.

Within clinics, eligible patients will be recruited consecutively from registers, an administrative sampling method enhancing feasibility and representativeness (Najafi et al., 2025). Inclusion criteria are: age ≥18 years; documented HIV diagnosis with ≥6 months on antiretroviral therapy; documented type 2 diabetes diagnosis; and attendance for routine chronic care (Ndhlovu, 2024). Exclusion criteria are severe cognitive impairment, an acute psychiatric condition requiring immediate referral, or inability to consent. A target of 720 participants (30 per clinic) provides power to detect a clinically meaningful difference in the primary outcome, accounting for intra-cluster correlation and anticipated attrition.

The intervention, the MIND-DZ package, is a multi-component, task-shifting model integrated into standard consultations (Pateña et al., 2025). It addresses documented unmet psychosocial needs, including distress, stigma, and care coordination challenges (Robson et al., 2024). Core components are training and supervising primary care nurses to use a locally adapted World Health Organisation Mental Health Gap Action Programme (mhGAP) Intervention Guide and to administer the Self-Reporting Questionnaire-20 (SRQ-20) for screening. Screening initiates a stepped-care protocol (Rukwava et al., 2025). For those screening positive, nurses use the mhGAP guide for further assessment (Tailor et al., 2024). First-line management includes nurse-delivered psychosocial interventions. For moderate-severe or non-responsive cases, a referral pathway to a specialist or tele-consultation is activated. All intervention patients receive brief psychoeducation on mental wellbeing and disease outcomes. Control clinics provide standard care, which may include ad-hoc mental health support, but without the structured screening, training, or protocol; they will be offered materials after trial completion.

Outcome data come from patient surveys and clinic records (Utete, 2024). Data collectors, blinded to allocation, administer surveys at baseline, 6, and 12 months (Aitcheson et al., 2024). The primary outcome is depressive symptom severity measured by the Patient Health Questionnaire-9 (PHQ-9). Key secondary outcomes are HIV viral load suppression and glycaemic control (HbA1c), from records within the 12-month follow-up. Other secondary outcomes include health-related quality of life (EQ-5D-5L), self-reported medication adherence, and retention in care. Implementation outcomes (feasibility, fidelity, acceptability) are captured via questionnaires and qualitative interviews.

Analysis will follow intention-to-treat principles (Akiba et al., 2026). Mixed-effects linear and logistic regression models will account for the hierarchical data and paired design, including treatment arm as a fixed effect, adjusting for baseline outcome values (where applicable), and including clinic pair as a random effect (Alsulamy, 2025). Subgroup analyses will explore effects by city, gender, and baseline disease control. A complementary process evaluation will analyse fidelity data to explain mechanisms and contextual barriers, such as urban overcrowding and resource constraints.

This methodology aims to generate robust evidence on clinical effectiveness and implementation in a low-resource setting (Chada et al., 2025). It addresses a critical care gap for the growing HIV-diabetes syndemic (Chen et al., 2024). Using existing infrastructure and nurse-led delivery enhances potential scalability within the Zimbabwean public health system.

# DISCUSSION

The evidence supporting the integration of mental health care into chronic infectious disease management in Zimbabwe is growing, yet key contextual mechanisms require clarification (Alsulamy, 2025). Research on the co-management of HIV and diabetes underscores the complex psychosocial needs of this population (Ndhlovu, 2024). For instance, studies highlight the trauma-related experiences of people living with HIV (Chireshe et al., 2025) and the specific psychosocial health needs of adults with type 2 diabetes (Chada et al., 2025). Complementary findings on the challenges of multimorbidity and healthcare access for ageing populations with HIV further illustrate the necessity of integrated models (Folorunsho & Suleman, 2025; Mupambireyi et al., 2025). However, these studies often leave unresolved the practical mechanisms for delivering such integrated care within Zimbabwe's primary health system, a gap this trial directly addresses.

The MIND-DZ trial is situated within a healthcare landscape where structural pressures significantly complicate chronic disease management (Pateña et al., 2025). Urban overcrowding in Harare, linked to heightened infectious disease transmission (Chirima, 2025), can exacerbate psychosocial stress and create logistical barriers to consistent clinic attendance. The trial's integrated, primary care-level model aims to mitigate these barriers by providing coordinated support in a single location, thereby reducing the burden on patients (Jani, 2024). Furthermore, the intervention's use of non-pharmacological strategies, such as problem-solving therapy, is informed by evidence supporting psychosocial interventions in chronic care (Mangezi et al., 2024). This approach is pertinent for addressing the identified needs of people with diabetes (Chada et al., 2025) and HIV (Chireshe et al., 2025), while task-shifting to NCD nurses builds sustainable capacity within existing systems.

Ultimately, this trial contributes critical evidence on operationalising integrated care in resource-constrained settings (Mangiza & Chakawa, 2024). Demonstrating improved outcomes could advocate for policy shifts, highlighting the strategic importance of investing in holistic models to improve wellbeing (Alsulamy, 2025). This is particularly urgent for an ageing population with HIV facing increasing multimorbidity (Folorunsho & Suleman, 2025), suggesting that successful integration could transform care for co-occurring chronic conditions across similar contexts.

**Table 1: Schedule of Key Activities and Milestones for the Cluster-Randomised Trial**

| Study Phase | Key Activities | Start Month | End Month | Primary Outcome(s) | Status (as of Q4 2024) |
|---|---|---|---|---|---|
| **Preparation & Training** | Protocol finalisation, staff recruitment, intervention training | 1 | 6 | Training completion rates, fidelity assessment | Completed |
| **Participant Recruitment & Baseline** | Cluster randomisation, participant screening, | 7 | 12 | Number enrolled, baseline HbA1c & PHQ-9 scores | Completed |

| | | | | | |
|---|---|---|---|---|---|
| | baseline data collection | | | | |
| **Intervention Delivery** | Integrated mental health and chronic disease care sessions | 13 | 24 | Session attendance rates, interim clinical measures | Ongoing |
| **Follow-up Assessments** | 6-month and 12-month post-baseline data collection | 19 | 30 | Change in PHQ-9 score (primary), change in HbA1c | Partially Completed (6-month) |
| **Data Analysis & Write-up** | Statistical analysis, manuscript preparation, dissemination | 25 | 36 | Final results, publication submissions | Pending |

*Note: Timeline is indicative; months are counted from project initiation.*

**Table 2: Sample Size Calculation Parameters for the Cluster-Randomised Trial**

| Parameter | Baseline Value | Assumed Change (Intervention) | Assumed Change (Control) | Power (1-β) | Alpha (α) | Required Clusters per Arm |
|---|---|---|---|---|---|---|
| **Primary Outcome (PHQ-9 Score)** | 15.2 (±4.1) | -4.5 (±3.8) | -1.5 (±3.5) | 0.90 | 0.05 | 12 |
| **Secondary Outcome (HbA1c %)** | 9.5 (±2.3) | -1.2 (±1.8) | -0.4 (±1.7) | 0.80 | 0.05 | 10 |
| **Secondary Outcome (ART Adherence >95%)** | 65% | +20% | +5% | 0.85 | 0.05 | 8 |
| **Cluster Size (Patients per Clinic)** | 25 [18-35] | N/A | N/A | N/A | N/A | N/A |
| **Intra-cluster Correlation (ICC)** | 0.05 | N/A | N/A | 0.90 | 0.05 | N/A |
| **Attrition Rate (Annual)** | 15% | N/A | N/A | N/A | N/A | N/A |

*Note: Assumptions based on pilot study data and systematic review evidence. PHQ-9: Patient Health Questionnaire-9; HbA1c: glycated haemoglobin; ART: antiretroviral therapy.*

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