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Implementation and assessment of a medication therapy management program in HIV patients at high risk of adverse drug events in Khartoum Sudan

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10/02/2026

Recruitment status
No longer recruiting

Registration date
16/02/2026

Overall study status
Ongoing

Last Edited
16/02/2026

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Protocol code
USM/JEPeM/PP/24100928

Study information

Scientific Title
Implementation and assessment of a medication therapy management program in HIV patients at high risk of adverse drug events in Khartoum Sudan

Study objectives
The main aim of this trial is to implement and assess an MTM program structured to prioritize patient safety the main components of the patient safety-oriented MTM model used in this study are medication reconciliation (MR), assessment of DRPs, and resolution of identified DRPs

Specific objectives:
1. To determine the effect of an MTM program vs usual care on antiretroviral therapy adherence rates among high-risk HIV patients over 6 months.
2. To compare the frequency and severity of adverse drug events reported by high-risk HIV patients receiving MTM services vs usual care.
3. To assess differences in viral load suppression (<200 copies/mL) between HIV patients who participate in the MTM program vs usual care.
4. To evaluate healthcare costs and resource utilization (hospitalizations, emergency visits) between MTM and usual care groups over 6 months.
5. To examine patient satisfaction with individualized pharmacist counseling and medication management received through the MTM program.
6. To identify barriers and facilitators to effective delivery of MTM services as perceived by patients and healthcare providers.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/07/2026, Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM) (Universiti Sains Malaysia Kampus Kesihatan, Kubang Kerian, Kelantan, 16150, Malaysia; +609 - 767 3000/2354/2362; jepem@usm.my), ref: USM/JEPeM/PP/24100928

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
To implement and assess a medication therapy management program and studying the positive impacts on medication safety, adherence, and patient satisfaction for HIV patients at high risk of ADEs in Khartoum, Sudan

Interventions
MTM Program Development
The MTM intervention is developed based on established pharmaceutical care principles, international MTM guidelines, and adaptation to the Sudanese healthcare context [18,19]. The intervention incorporates evidence-based components while addressing local resource constraints and cultural considerations.

Key development activities include:
1. Literature Review: Comprehensive review of MTM interventions in HIV care and resource-limited settings
2. Stakeholder Engagement: Consultations with HIV care providers, pharmacists, patients, and healthcare administrators
3. Cultural Adaptation: Modification of intervention components to align with Sudanese healthcare practices and patient preferences
4. Pilot Testing: Small-scale pilot with 20 patients to refine procedures and identify implementation challenges
5. Training Material Development: Creation of standardized protocols, forms, and training materials

MTM Service Components
The MTM intervention consists of five core components delivered over 6 months:
Component 1: Comprehensive Medication Review (CMR)
A systematic evaluation of all medications taken by the participant, including:
- Complete medication history including prescription drugs, over-the-counter medications, and traditional medicines
- Assessment of medication appropriateness, effectiveness, safety, and adherence
- Identification of drug-related problems using standardized classification system
- Documentation of allergies, adverse reactions, and contraindications

Component 2: Personal Medication Record (PMR)
Creation and maintenance of a comprehensive, accurate medication list including:
- All current medications with doses, frequencies, and indications
- Prescriber information and contact details
- Pharmacy information and refill schedules
- Special instructions and precautions
- Regular updates at each MTM encounter

Component 3: Medication-Related Action Plan (MAP)
Development of individualized plans to address identified medication-related problems:
- Prioritized list of medication-related issues requiring attention
- Specific action steps with timelines and responsible parties
- Patient education priorities and goals
- Monitoring parameters and follow-up plans
- Communication plan with other healthcare providers

Component 4: Intervention and Referral
Implementation of interventions to resolve drug-related problems:
- Direct patient education and counseling
- Adherence support and barrier identification
- Communication with prescribers regarding medication issues
- Coordination with other healthcare team members
- Referrals to appropriate services when needed

Component 5: Documentation and Follow-up
Systematic documentation and monitoring of MTM activities:
- Standardized documentation of all MTM encounters
- Progress monitoring toward therapeutic goals
- Outcome assessment and intervention effectiveness evaluation
- Continuous quality improvement based on outcomes data

Intervention Schedule and Intensity
The MTM intervention is delivered according to the following schedule:
- Initial MTM Visit (Month 0) : Comprehensive 60-90 minute session including complete medication review, problem identification, and action plan development
- Follow-up MTM Visit (Month 3): 45-60 minute session focusing on progress review, problem resolution, and plan updates
- Interim Contact (Month 1.5): 15-20 minute telephone consultation to address urgent issues and provide adherence support
- Final Assessment (Month 6): 30-45 minute session for outcome assessment and transition planning

Additional contacts are provided as needed based on participant needs and identified medication-related problems. All MTM services are provided by trained clinical pharmacists using standardized protocols and documentation forms.

MTM Provider Training
Clinical pharmacists delivering MTM services undergo comprehensive training including:
1. HIV Pharmacotherapy : 16-hour training covering HIV pathophysiology, antiretroviral medications, drug interactions, and monitoring parameters
2. MTM Methodology : 12-hour training on pharmaceutical care principles, MTM service delivery, and documentation requirements
3. Communication Skills : 8-hour training on patient counseling, motivational interviewing, and cultural competency
4. Research Procedures : 4-hour training on study protocols, data collection, and quality assurance procedures
5. Ongoing Support : Monthly supervision sessions and quarterly refresher training throughout the study period

Training materials are developed in Arabic and English with case studies relevant to the Sudanese context. Competency assessments ensure that all MTM providers meet minimum standards before delivering services to study participants.

Quality Assurance
Multiple quality assurance measures ensure consistent and high-quality MTM service delivery:
1. Standardized Protocols: Detailed protocols for all MTM activities with step-by-step procedures
2. Documentation Standards: Standardized forms and templates for consistent documentation

3. Supervision and Monitoring : Regular supervision of MTM providers with review of documentation and patient encounters
4. Fidelity Assessment : Systematic assessment of intervention fidelity using standardized checklists
5. Continuous Improvement : Regular review of intervention delivery with modifications as needed based on implementation experience

Control Group (Usual Care)
Participants randomized to the control group receive usual HIV care as provided at participating clinics. Usual care includes:
1. Routine Medical Visits: Regular physician consultations every 3-6 months for clinical assessment and medication management
2. Laboratory Monitoring: Routine viral load and CD4 count monitoring according to national guidelines
3. Basic Adherence Counseling: Standard adherence counseling provided by nurses or counselors during clinic visits
4. Medication Dispensing: Antiretroviral medication dispensing through hospital pharmacies with basic counseling
5. Opportunistic Infection Management: Treatment and prevention of HIV-related complications
6. Psychosocial Support: Access to counseling and support services as available

Usual Care Standardization
To ensure consistency across study sites, usual care practices are documented and standardized where possible:
1. Care Protocols: Review and documentation of existing HIV care protocols at each site
2. Provider Training: Brief training for usual care providers on study procedures and outcome measurement
3. Quality Monitoring: Regular monitoring of usual care delivery to ensure consistency
4. Documentation: Standardized documentation of usual care services received by control group participants

Contamination Prevention
Measures are implemented to prevent contamination between intervention and control groups:
1. Provider Separation: Different pharmacists provide MTM services and usual care medication counseling
2. Patient Education: Clear communication to control group participants about their assigned group and services they will receive
3. Monitoring: Regular monitoring for evidence of MTM-type services being provided to control group participants
4. Site Coordination: Coordination with site staff to ensure intervention components are not inadvertently provided to control participants

Intervention Type
Behavioural

Primary outcome(s)
1. Medication adherence measured using Proportion of Days Covered from pharmacy refill records at 3 months and 6 months

Key secondary outcome(s))
1. Viral suppression measured using HIV RNA testing at 6 months

2. CD4 count measured using mean change from baseline at 6 months

3. Adverse drug events measured using incidence and severity assessed by the Naranjo criteria at 3 months and 6 months

4. Drugrelated problems measured using the PCNE classification at 3 months and 6 months

5. Hospitalizations measured using number and duration of hospitalizations at 6 months

6. Emergency visits measured using number of emergency visits at 6 months

7. Quality of life measured using EQ5D5L at 6 months

8. Satisfaction measured using the pharmaceutical care satisfaction questionnaire at 6 months

9. Selfefficacy measured using HIVASES at 6 months

10. Medication knowledge measured using a validated questionnaire at 3 months and 6 months

11. Direct medical costs measured using data on hospitalizations, visits, laboratory tests, and medications at 6 months

12. Costeffectiveness measured using cost per QALY gained at 6 months

Completion date
26/04/2026

Eligibility

Key inclusion criteria
1. HIV-positive individuals aged 18 years and older.
2. Primary use of English or Arabic for oral and written communication.
3. ≥3 comorbid conditions associated with increased healthcare utilization (e.g., CHF, DM, COPD, HTN, opportunistic infections).
4. ≥2 visits to a physician or advanced practice provider at the study site clinic over the past year.
5. ≥8 chronic prescription medications over the 6 months prior to study enrollment.
6. Have a telephone line available for at least 6 months.
7. Willingness to participate in the study and provide informed consent.
8. Situation placing the patient at risk for a drug-related problem (DRP): Change in medication, new physician visit, ER visit, hospitalization, invasive procedure within the last 30 days, or seeing 3 or more providers within 12 months.

Part 2: MTM Provider (Pharmacist Population)
1. Pharmacists involved in delivering MTM services to HIV patients.
2. At least six months of experience providing MTM services to HIV patients.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
692

Key exclusion criteria
1. Terminal condition with life expectancy ≤6 months
2. Previous enrolment in the MTM program with medication reconciliation or assessment for DRPs within 12 months
3. Inability to provide informed consent or participate in the study due to cognitive impairment or other reasons

Date of first enrolment
10/01/2022

Date of final enrolment
26/01/2024

Locations

Countries of recruitment
Sudan

Sponsor information

Organisation
Universiti Sains Malaysia

ROR
https://ror.org/02rgb2k63

Funder(s)

Funder type

Funder Name
Universiti Sains Malaysia

Alternative Name(s)
University of Science, Malaysia, Universiti Sains Malaysia (USM), Universiti Sains Malaysia | George Town, Malaysia | USM, usmofficial1969, University Sains Malaysia (USM), University Sains Malaysia, Science University of Malaysia, USM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			16/02/2026	No	No
Protocol file	version 2.0	15/03/2025	16/02/2026	No	No