STUDY PROTOCOL
Implementation and Assessment of a Medication Therapy Management Program in HIV Patients at High Risk of Adverse Drug Events at Khartoum, Sudan

Protocol Version: 2.0

Date: 15 March 2025

Protocol ID: HIV-MTM-SUDAN-001

Contents

1. TITLE PAGE

Field	Information
Title	Implementation and Assessment of a Medication Therapy Management Program in HIV Patients at High Risk of Adverse Drug Events at Khartoum, Sudan
Protocol Number	HIV-MTM-SUDAN-001 (Version 2.0, 15 March 2025)

Field	Information
Principal Investigator	Dr. Nada Abdelrahman Mohammed Ibrahim
Co-Investigators	Assoc. Prof. Dr. Hasni Arsad, Dr. Mohd Yusmaidie Aziz, Dr. Christina Malini Christopher
Study Sponsor	Universiti Sains Malaysia (USM), Advanced Medical and Dental Institute, 13200 Kepala Batas, Pulau Pinang, Malaysia
Collaborating Institution	Federal Ministry of Health, Sudan
Ethics Approval	USM/JEPeM/PP/24100928 (18 July 2025 - 17 July 2026) FMOH Sudan Final Committee Decision No. (51120) – 12-June 2020
Study Sites	Khartoum Teaching Hospital, Omdurman Teaching Hospital, Bahri Ibrahim Malik Teaching Hospital, Sudan
Target Sample Size	692 participants (346 per group)
Study Duration	30 months (including 24-month follow-up)
Primary Objective	Evaluate effectiveness of pharmacist-led MTM on medication adherence
Study Phase	Not applicable (Health Services Research)

2. PROTOCOL SUMMARY

Section	Description
Background	HIV remains a significant health challenge in Sudan with suboptimal medication adherence and limited pharmaceutical care services. High-risk patients (those with multiple comorbidities and complex regimens) are particularly vulnerable to adverse drug events and poor outcomes.
Objective	To implement and evaluate a pharmacist-led Medication Therapy Management (MTM) program for high-risk HIV patients in Khartoum, Sudan compared to usual care.
Design	Parallel-group, open-label randomized controlled trial with mixed-methods evaluation
Population	Adults ≥18 years with HIV receiving ART, meeting high-risk criteria (≥8 medications, ≥3 comorbidities, history of ADEs, suboptimal adherence, or detectable viral load)
Intervention	Structured MTM including comprehensive medication review, personal medication record, medication-related action plan, adherence counseling, and follow-up
Control	Usual care (standard physician-led HIV care without structured pharmaceutical services)
Primary Outcome	Medication adherence (Proportion of Days Covered ≥95%) at 6 months
Secondary Outcomes	Viral suppression, CD4 count, ADEs, healthcare utilization, costs, patient satisfaction, quality of life

Section	Description
Sample Size	692 (346 per arm) with 80% power to detect 10% difference in adherence
Analysis	Intention-to-treat with linear mixed-effects models; thematic analysis for qualitative data

3. INTRODUCTION & RATIONALE

3.1 Background

Human Immunodeficiency Virus (HIV) remains a significant global health challenge, with approximately 38.4 million people living with HIV worldwide. Sub-Saharan Africa bears 67% of the global burden, and Sudan faces unique challenges including conflict, economic instability, and critical shortages of clinical pharmacists.

Medication adherence rates in Sudan often fall below the 95% threshold required for viral suppression. High-risk patients—those with multiple comorbidities, complex regimens, or previous treatment failure—are particularly vulnerable to drug-related problems, adverse events, and poor outcomes.

3.2 Rationale

No structured Medication Therapy Management program currently exists for HIV patients in Sudan. International evidence demonstrates pharmacist-led interventions improve outcomes, but context-specific evidence is needed for Sudan. This study addresses this gap by evaluating MTM effectiveness, feasibility, and implementation factors in the Sudanese healthcare context.

3.3 Theoretical Framework

The study is grounded in pharmaceutical care theory (Hepler & Strand) emphasizing pharmacist responsibility for drug therapy outcomes, and implementation science principles using the Consolidated Framework for Implementation Research (CFIR).

4. STUDY OBJECTIVES

4.1 Primary Objective

To evaluate the effectiveness of a structured MTM program compared to usual care in improving medication adherence among high-risk HIV patients over 6 months.

4.2 Secondary Objectives

1. Compare viral load suppression rates (<200 copies/mL) between groups
2. Assess CD4+ cell count changes
3. Quantify drug-related problems identified and resolved
4. Compare adverse drug event frequency and severity
5. Evaluate healthcare resource utilization
6. Assess cost-effectiveness
7. Examine patient satisfaction and quality of life
8. Identify implementation barriers and facilitators

5. STUDY DESIGN

This is a **parallel-group, open-label randomized controlled trial** with three arms:

Arm	Group	n	Intervention
1	Control	346	Usual Care only
2	Basic MTM	346	MTM + Usual Care

Design Features:

- 1:1 allocation ratio

- Stratified by site and baseline viral suppression
- Block randomization with variable block sizes (4, 6, 8)
- 6-month follow-up period
- Mixed-methods integration (quantitative RCT + qualitative interviews)

6. STUDY SETTING

Three HIV care centers in Khartoum State, Sudan:

Site	Location	Active Patients	Services
Khartoum Teaching Hospital HIV Clinic	Khartoum	2,500	Comprehensive HIV care, lab monitoring
Omdurman Teaching Hospital HIV Clinic	Omdurman	1,800	HIV/TB integrated services
Ibrahim Malik Teaching Hospital(Bahri)	Khartoum	1,200	Complex HIV cases, comorbidities

All sites provide standard HIV care including ART, routine monitoring, and basic adherence counseling.

7. PARTICIPANTS

7.1 Inclusion Criteria

1. Age ≥18 years
2. Confirmed HIV-positive diagnosis
3. Receiving ART for ≥3 months

4. Meet ≥2 high-risk criteria:
    - ≥8 chronic medications
    - ≥3 chronic comorbid conditions
    - History of ADEs in past 12 months
    - Viral load >200 copies/mL in past 6 months
    - Self-reported adherence <95% or missed appointments
5. Able to communicate in Arabic or English
6. Willing to provide informed consent

7.2 Exclusion Criteria

1. Age <18 years
2. Severe cognitive impairment
3. Pregnancy
4. Life expectancy <12 months
5. Participation in other medication intervention studies
6. Plans to relocate outside Khartoum State

8. INTERVENTIONS

8.1 MTM Intervention Components

Component	Description
Comprehensive Medication Review	Systematic evaluation of all medications (prescription, OTC, traditional) for appropriateness, effectiveness, safety, adherence
Personal Medication Record	Comprehensive medication list with doses, frequencies, indications, prescriber information, refill schedules

Component	Description
Medication-Related Action Plan	Individualized plan addressing identified problems with action steps, timelines, monitoring parameters
Intervention & Referral	Patient education, adherence support, prescriber communication, referrals
Documentation & Follow-up	Standardized documentation, progress monitoring, outcome assessment

8.2 Intervention Schedule

Visit	Timing	Duration	Activities
Initial	Month 0	60-90 min	Comprehensive review, problem identification, action plan
Follow-up 1	Month 3	45-60 min	Progress review, problem resolution, plan updates
Interim Contact	Month 1.5	15-20 min	Telephone consultation, adherence support
Final Assessment	Month 6	30-45 min	Outcome assessment, transition planning

8.3 Control Group (Usual Care)

- Routine physician consultations every 3-6 months
- Laboratory monitoring per national guidelines
- Basic adherence counseling by nurses/counselors
- Medication dispensing with basic counseling

- Access to psychosocial support services

8.4 MTM Provider Training

Training Module	Duration
HIV Pharmacotherapy	16 hours
MTM Methodology	12 hours
Communication Skills	8 hours
Research Procedures	4 hours
Ongoing Support	Monthly supervision

9. OUTCOME MEASURES

9.1 Primary Outcome

Outcome	Measure	Timepoint	Definition
Medication Adherence	Proportion of Days Covered (PDC) from pharmacy refill records	3, 6 months	PDC = (Days with medication available / Days in period) × 100; ≥95% = optimal

9.2 Secondary Outcomes

Domain	Outcome	Measure	Timepoint
Clinical	Viral suppression	HIV RNA <200 copies/mL	6 months

Domain	Outcome	Measure	Timepoint
	CD4 count	Mean change from baseline	6 months
Safety	ADEs	Incidence, severity (Naranjo criteria)	3, 6 months
	Drug-related problems	PCNE classification	3, 6 months
Utilization	Hospitalizations	Number, duration	6 months
	Emergency visits	Number	6 months
Patient-reported	Quality of life	EQ-5D-5L	6 months
	Satisfaction	Pharmaceutical care satisfaction questionnaire	6 months
	Self-efficacy	HIV-ASES	6 months
	Medication knowledge	Validated questionnaire	3, 6 months
Economic	Direct medical costs	Hospitalizations, visits, labs, medications	6 months
	Cost-effectiveness	Cost per QALY gained	6 months

10. SAMPLE SIZE CALCULATION

Parameter	Value
Expected adherence (control)	75%
Expected adherence (intervention)	85%
Effect size	10 percentage points
Power	80%
Alpha	0.05 (two-sided)
Allocation ratio	1:1
Calculated sample size (per group)	294
Anticipated loss to follow-up	15%
Target sample size (per group)	**346**
Total sample size	**692**

Formula used: $n = (Z\alpha/2 + Z\beta)^2 \times [p1(1-p1) + p2(1-p2)] / (p1-p2)^2$

11. RANDOMIZATION & BLINDING

11.1 Randomization Method

- Computer-generated randomization sequence
- 1:1 allocation

- Stratified by site and viral load status
- Block randomization with variable block sizes (4, 6, 8)

11.2 Allocation Concealment

- Sequentially numbered, opaque, sealed envelopes
- Prepared by independent statistician
- Opened only after eligibility confirmed and baseline data collected

11.3 Blinding

Role	Blinded?
Participants	No (open-label)
MTM providers	No
Outcome assessors	Yes
Laboratory personnel	Yes
Data analysts	Yes

12. DATA COLLECTION

12.1 Quantitative Data Collection Schedule

Measure	Baseline	Month 3	Month 6
Demographics	✓		
Clinical history	✓		

Measure	Baseline	Month 3	Month 6
Medication list	✓	✓	✓
Adherence (PDC)		✓	✓
Adherence (MARS-5)	✓	✓	✓
Viral load	✓		✓
CD4 count	✓		✓
ADEs	✓	✓	✓
Healthcare utilization	✓	✓	✓
Quality of life (EQ-5D-5L)	✓		✓
Patient satisfaction			✓
Self-efficacy (HIV-ASES)	✓		✓
Medication knowledge	✓	✓	✓
Costs			✓

12.2 Qualitative Data Collection

Method	Sample	Purpose
Patient interviews	20-25 MTM participants	Explore experiences, barriers, facilitators
Provider interviews	All MTM pharmacists (6) + 15 other providers	Implementation perspectives
Focus groups	3-4 groups (6-8 each) control participants	Medication management challenges

12.3 Data Management

- REDCap database with access controls
- Double data entry for key variables
- Range and consistency checks
- Regular backups
- Audio recording and transcription for qualitative data
- NVivo for qualitative analysis

13. DATA ANALYSIS

13.1 Quantitative Analysis

Analysis	Method
Descriptive	Means ± SD, frequencies, proportions
Primary outcome	Linear mixed-effects models (intention-to-treat)

Analysis	Method
Binary outcomes	Logistic regression with GEE
Count outcomes	Negative binomial regression
Time-to-event	Cox proportional hazards
Subgroup analyses	Interaction tests
Missing data	Multiple imputation, sensitivity analyses
Economic analysis	Incremental cost-effectiveness ratios

13.2 Qualitative Analysis

- Thematic analysis using inductive approach
- Independent coding by two researchers
- Framework guided by CFIR
- Member checking, peer review, audit trail

13.3 Mixed-Methods Integration

- Convergent parallel design
- Joint displays
- Narrative integration
- Case study analysis

14. ETHICAL CONSIDERATIONS

14.1 Ethics Approvals

Committee	Reference	Date
USM JEPeM	USM/JEPeM/PP/24100928	18 July 2025
FMOH Sudan Research Ethics Committee	51120	12 June 2020
Khartoum State Ministry of Health	Provided	
Individual hospital ethics committees	Provided	

14.2 Informed Consent Process

- Information provided in participant's preferred language (Arabic/English)
- Minimum 24 hours for consideration
- Opportunity for questions
- Witness for illiterate participants
- Clear emphasis on voluntary participation
- Right to withdraw without affecting care

14.3 Confidentiality Measures

- De-identification with study ID numbers
- Role-based access controls
- Encrypted data transmission and storage
- Secure locked storage for paper records
- Confidentiality training for all staff
- Private spaces for all research activities

14.4 Risk-Benefit Assessment

Risks	Mitigation
Confidentiality breach	Strict protocols, staff training, secure systems
Time burden	Flexible scheduling
Psychological distress	Access to counseling
Disappointment (control)	Post-study MTM offer
Benefits	
Enhanced pharmaceutical care (intervention)	
Improved clinical monitoring (all)	
Increased medication knowledge	
Contribution to knowledge	

14.5 Data Safety Monitoring

- Independent DSMB with clinician, statistician, community representative
- Quarterly reviews
- Standardized adverse event reporting
- SAE reporting within 24 hours

15. DISSEMINATION PLAN

Audience	Method
Scientific community	Peer-reviewed publications, conferences
Policymakers (FMOH Sudan)	Policy briefs, presentations
Healthcare providers	Training materials, workshops
Participants	Lay summaries
General public	Media engagement

16. REFERENCES (Selected)

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5. Damschroder LJ, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.
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17. APPENDICES

APPENDIX A: Participant Information Sheet (English)

Research Title: IMPLEMENTATION AND ASSESSMENT OF A MEDICATION THERAPY MANAGEMENT PROGRAM FOR HIV PATIENT AT HIGH RISK OF ADVERSE DRUG EVENTS IN KHARTOUM SUDAN

Principal Investigator: NADA ABDELRAHMAN MOHAMED IBRAHIM (P-IPD0025/21(R))

Co-Investigators: Dr. Hasni bin Arsad (Main Supervisor), Dr. Mohd Yusmaidie bin Aziz (Co-Supervisor)

INTRODUCTION

You are invited to take part voluntarily in interventional research as an ambulatory care patient at (Omdurman/Bahri/Khartoum center). This research will focus on the implementation and assessment of a medication therapy management program for patients at high risk of adverse drug events in Khartoum, Sudan. This will be a randomized controlled clinical trial comparing three patient groups in the three main centers in Khartoum state to evaluate the effect of a patient safety pharmacist-led medication therapy program involving comprehensive medication review, drug-related problems identification and resolution, and a personal medication list on adverse drug events and medical visits. The study will determine whether a medication therapy management program with access to information transcribed from patient medical records can improve patient safety and care.

It is important that you read and understand this research information before agreeing to participate in this study. You will receive a copy of this form to keep for your records if you agree to participate. Your participation in this study is expected to take 15-20 minutes of your time to finish all data collection each month. This study is estimated to include up to 900 participants.

PURPOSE OF THE STUDY

The purpose of this study is to determine and evaluate the effect of a pharmacist-led patient safety program to improve patient care and safety.

PARTICIPANTS CRITERIA

The research team members will discuss your eligibility to participate in this study. It is important that you are completely truthful with the staff including your health history.

This study will include individuals who meet the following criteria:

- **Age:** Must be 18 years or older at the time of enrollment
- **Language Proficiency:** Primary use of English or Arabic for both oral and written communication
- **Health Conditions:** Must have three or more comorbid conditions associated with increased healthcare utilization
- **Healthcare Visits:** Must have had two or more visits to a physician or advanced practice provider at the study site clinic within the past year
- **Chronic Medications:** Must be prescribed eight or more chronic medications over the six months preceding study enrollment
- **Telephone Access:** Must have a telephone line available for at least six months

Exclusions: Individuals under 18 years of age or who cannot effectively communicate in English or Arabic.

STUDY PROCEDURES

Participants will be interviewed about their medications, the care provided through the intervention program, and their satisfaction with the services delivered. The program team will conduct medication reconciliation to assess the safety and appropriate use of drug treatments.

Procedure of Intervention: Participants will engage in monthly sessions over a 6-month period. Each session will last 15 to 20 minutes and will focus on reviewing medications, discussing any drug-related problems, and providing counseling to improve medication management.

Randomization Statement: Participants will be randomized into groups to ensure unbiased results. Randomization will occur after the initial eligibility screening, and participants will be notified of their assigned group within one week.

Termination of Participation: Participation may be terminated under the following circumstances:

- If a participant does not adhere to study protocols
- If significant health issues arise that may compromise the participant's safety
- If the participant chooses to withdraw for any reason

Expected Duration of Participation: The total expected duration of participation is 6 months. Participants will attend monthly sessions, with each session lasting 15 to 20 minutes. This includes regular follow-ups and assessments throughout the study period.

RISKS

No risks are anticipated from participation in this study. All information will be considered confidential and secure. It is essential that you understand the study, its procedures, and any potential impacts on your health and well-being before agreeing to participate.

REPORTING HEALTH EXPERIENCES

Please contact the following researcher at any time if you experience any health problems, either directly or indirectly related to this study:

Dr. Nada Ibrahim [MMC Registration No. R-P-007485]
Phone: 0096658860 or +249 90 624 018

PARTICIPATION IN THE STUDY

Your participation in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation at any time, without any penalty or loss of benefits to which you are otherwise entitled. Your participation may also be stopped by the research team without your consent if you have violated the study eligibility criteria. The research team member will discuss with you if the matter arises.

POSSIBLE BENEFITS

- You may receive excellent counseling about your treatment and improvement in the services you need
- This study findings may benefit the community by delivering high-quality medication therapy services
- You will not receive any compensation from this study; however, you may receive reimbursement for travel costs incurred during the study duration

QUESTIONS

If you have any questions about this study or your rights, please contact:

Dr. Nada Ibrahim [MMC Registration No. R-P-007485]
Phone: 0096658860 or +249 90 624 0182
Department of Pharmacy Practice and Clinical Pharmacy, Khartoum, Sudan

If you have any questions regarding the Ethical Approval or any issue related to this study, please contact:

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Division of Research & Innovation (R&I), USM Health Campus
Tel. No.: 09-767 2354 / 09-767 2362
Email: bazlan@usm.my

OR

Miss Nor Amira Khurshid Ahmed
Secretariat of Human Research Ethics Committee USM
Research Creativity & Management Office (RCMO), USM Main Campus, Penang
Tel. No.: 04-6536537
Email: noramira@usm.my

CONFIDENTIALITY

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may be held and processed on a computer. Only research team members are authorized to access your information.

By signing this consent form, you authorize the record review, information storage and data process described above.

APPENDIX B: Participant Information Sheet (Arabic)

عنوان البحث :تنفيذ وتقييم برنامج إدارة العلاج الدوائي للمرضى المعرضين لمخاطر الأحداث السلبية للدواء في الخرطوم، السودان

اسم الباحث الرئيسي :ندى عبد الرحمن محمد إبراهيم((P-IPD0025/21(R

الباحثون المساعدون :د. حسني بن أرسد (المشرف الرئيسي)، د. محمد يوسمايدي بن عزيز (المشرف المساعد)

المقدمة

أنت مدعو للمشاركة طوعًا في هذا البحث (بحث تدخلي). يتعلق هذا البحث بتنفيذ وتقييم برنامج إدارة العلاج الدوائي للمرضى المعرضين لمخاطر الأحداث السلبية للدواء في الخرطوم، السودان. هذه تجربة سريرية عشوائية محكومة تقارن بين ثلاث مجموعات من المرضى في ثلاثة مراكز رئيسية في ولاية الخرطوم لتقييم تأثير برنامج إدارة العلاج الدوائي الذي يقوده صيدلي لسلامة المرضى والذي يتضمن مراجعة شاملة للأدوية، وتحديد وحل المشاكل المتعلقة بالأدوية، وقائمة الأدوية الشخصية على الأحداث السلبية للدواء وزيارات الطبيب. سيحدد هذا البحث ما إذا كان برنامج إدارة العلاج الدوائي مع الوصول إلى المعلومات المستخلصة من السجلات الطبية للمرضى يحسن سلامة ورعاية المرضى.

من المهم أن تقرأ وتفهم هذه المعلومات قبل أن توافق على المشاركة في هذه الدراسة. ستتلقى نسخة من هذا النموذج للاحتفاظ بها في سجلاتك إذا وافقت على المشاركة. من المتوقع أن تستغرق مشاركتك في هذه الدراسة من 15 إلى 20 دقيقة من وقتك لإكمال جميع جمع البيانات كل شهر. من المتوقع أن تشمل هذه الدراسة ما يصل إلى 900 مشارك.

هدف الدراسة

يهدف هذا البحث إلى تقييم تأثير برنامج سلامة المرضى الذي يقوده صيدلي لتحسين رعاية المرضى وسلامتهم.

معايير المشاركين

سيناقش أعضاء فريق البحث أهليتك للمشاركة في هذه الدراسة. من المهم أن تكون صادقًا تمامًا مع الموظفين بما في ذلك تاريخك الصحي.

ستشمل هذه الدراسة الأفراد الذين يستوفون المعايير التالية:

- **العمر :**يجب أن يكون 18 عامًا أو أكثر عند التسجيل
- **إجادة اللغة :**الاستخدام الأساسي للغة الإنجليزية أو العربية للتواصل الشفهي والكتابي
- **الحالات الصحية :**يجب أن يكون لديهم ثلاث حالات مرضية مصاحبة أو أكثر مرتبطة بزيادة استخدام الرعاية الصحية
- **زيارات الرعاية الصحية :**يجب أن يكون لديهم زيارتان أو أكثر لطبيب في عيادة موقع الدراسة خلال العام الماضي
- **الأدوية المزمنة :**يجب أن يكون لديهم 8 أدوية وصفية مزمنة أو أكثر خلال الستة أشهر السابقة للتسجيل في الدراسة
- **توفر الهاتف :**يجب أن يكون لديهم خط هاتف متاح لمدة لا تقل عن 6 أشهر

الاستبعاد :الأفراد الذين تقل أعمارهم عن 18 عامًا أو غير القادرين على التواصل شفهيًا وكتابيًا باللغتين الإنجليزية أو العربية.

إجراءات الدراسة

سيتم استجواب المشاركين في الدراسة حول أدويتهم ورعاية برنامج التدخل ورضاهم عن الخدمة المقدمة. من خلال إجراء مراجعة دوائية مع فريق البرنامج لتقييم سلامة علاجهم الدوائي والاستخدام المناسب.

إجراءات التدخل :سيشارك المشاركون في جلسات شهرية على مدى 6 أشهر. ستستغرق كل جلسة من 15 إلى 20 دقيقة وستركز على مراجعة الأدوية، ومناقشة أي مشاكل متعلقة بالدواء، وتقديم المشورة لتحسين إدارة الدواء.

بيان العشوائية :سيتم توزيع المشاركين عشوائيًا إلى مجموعات لضمان نتائج غير متحيزة. سيحدث التوزيع العشوائي بعد فحص الأهلية الأولي، وسيتم إخطار المشاركين بالمجموعة المخصصة لهم في غضون أسبوع واحد.

إنهاء المشاركة :يمكن إنهاء المشاركة في الحالات التالية:

- إذا لم يلتزم المشارك ببروتوكولات الدراسة
- إذا ظهرت مشاكل صحية كبيرة قد تعرض سلامة المشارك للخطر
- إذا اختار المشارك الانسحاب لأي سبب

المدة المتوقعة للمشاركة :إجمالي المدة المتوقعة للمشاركة هي 6 أشهر. سيحضر المشاركون جلسات شهرية، مدة كل جلسة من 15 إلى 20 دقيقة. وهذا يشمل المتابعات والتقييمات المنتظمة طوال فترة الدراسة.

المخاطر

لا توجد مخاطر متوقعة من المشاركة في هذه الدراسة. جميع المعلومات ستكون سرية وآمنة. من الضروري أن تفهم الدراسة وإجراءاتها وأي تأثيرات محتملة على صحتك ورفاهيتك قبل الموافقة على المشاركة.

الإبلاغ عن التجارب الصحية

يرجى الاتصال بالباحث التالي في أي وقت إذا واجهت أي مشكلة صحية، سواء كانت مرتبطة مباشرة أو غير مباشرة بهذه الدراسة:

د. ندى إبراهيم
رقم التسجيلR-P-007485 :
هاتف: 0096658860 أو +249 90 624 0182

المشاركة في الدراسة

مشاركتك في هذه الدراسة تطوعية تمامًا. يمكنك رفض المشاركة في الدراسة أو إيقاف مشاركتك في أي وقت، دون أي عقوبة أو فقدان للمزايا التي تستحقها. يمكن أيضًا إيقاف مشاركتك من قبل فريق البحث دون موافقتك إذا انتهكت معايير أهلية الدراسة. سيناقش معك أعضاء فريق البحث إذا ظهرت المسألة.

الفوائد المحتملة

- قد تحصل على استشارة ممتازة حول علاجك وتحسين في الخدمة التي تحتاجها
- قد تفيد نتائج هذه الدراسة المجتمع من خلال تقديم خدمة إدارة علاج دوائي عالية الجودة
- لن تتلقى أي تعويض مالي من هذه الدراسة؛ ومع ذلك، قد تحصل على تعويض عن تكاليف التنقل خلال مدة الدراسة

الأسئلة

إذا كان لديك أي سؤال حول هذه الدراسة أو حقوقك، يرجى الاتصال بـ:

د. ندى إبراهيم
رقم التسجيلR-P-007485 :
هاتف: 0096658860 أو +249 90 624 0182
قسم ممارسة الصيدلة والصيدلة السريرية، الخرطوم، السودان

إذا كان لديك أي أسئلة تتعلق بالموافقة الأخلاقية أو أي قضية تتعلق بهذه الدراسة، يرجى الاتصال بـ:

السيد محمد بازلان حفيظ مكريم
أمين لجنة الأخلاقيات للبحث البشريUSM
قسم البحث والابتكار، حرم الصحةUSM

رقم الهاتف: 2362 767-09 / 2354 767-09
البريد الإلكترونيbazlan@usm.my :

أو

السيدة نور أميرة خرشيد أحمد
أمانة لجنة الأخلاقيات للبحث البشريUSM
مكتب إدارة البحث والإبداع، الحرم الرئيسيUSM ، بينانغ
رقم الهاتف: 04-6536537
البريد الإلكترونيnoramira@usm.my :

السرية

سيتم الاحتفاظ بمعلوماتك سرية من قبل الباحثين ولن يتم الكشف عنها علنًا إلا إذا كان الكشف مطلوبًا بموجب القانون.

سيتم نشر البيانات المستمدة من هذه الدراسة التي لا تحدد هويتك لأغراض المعرفة.

يمكن مراجعة سجلاتك الأصلية من قبل الباحث، ولجنة المراجعة الأخلاقية لهذه الدراسة، والسلطات التنظيمية لغرض التحقق من إجراءات الدراسة و/أو البيانات. قد يتم الاحتفاظ بمعلوماتك ومعالجتها على جهاز كمبيوتر. فقط أعضاء فريق البحث مخول لهم الوصول إلى معلوماتك.

بالتوقيع على نموذج الموافقة هذا، فإنك تفوض مراجعة السجلات، وتخزين المعلومات، ومعالجة البيانات كما هو موضح أعلاه.

APPENDIX C: Informed Consent Form (English)

Research Title: IMPLEMENTATION AND ASSESSMENT OF A MEDICATION THERAPY MANAGEMENT PROGRAM FOR HIV PATIENT AT HIGH RISK OF ADVERSE DRUG EVENTS IN KHARTOUM SUDAN

Researcher's Name: NADA ABDELRAHMAN MOHAMED IBRAHIM

To become a part of this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form including any information regarding the risk in this study and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at any time.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

Participant Name:_____

Participant I.C No.:_____

Signature of Participant or Legal Representative:_____

Date (dd/MM/yy):_____ / _____ / _____

Name of Individual Conducting Consent Discussion:_____

Signature of Individual Conducting Consent Discussion:_____

Date (dd/MM/yy):_____ / _____ / _____

Name & Signature of Witness: _____

Date (dd/MM/yy): _____ / _____ / _____

APPENDIX D: Informed Consent Form (Arabic)

نموذج الموافقة المستنيرة

عنوان البحث :تنفيذ وتقييم برنامج إدارة العلاج الدوائي للمرضى المعرضين لمخاطر الأحداث السلبية للدواء في الخرطوم، السودان

اسم الباحث :ندى عبد الرحمن محمد إبراهيم

لكي تصبح جزءًا من هذه الدراسة، يجب عليك أو ممثل قانوني توقيع هذه الصفحة. من خلال توقيع هذه الصفحة، أؤكد ما يلي:

- لقد قرأت جميع المعلومات في نموذج معلومات المريض والموافقة هذا بما في ذلك أي معلومات تتعلق بالمخاطر في هذه الدراسة وكان لدي الوقت للتفكير فيها.
- تم الرد على جميع أسئلتي بما يرضيني.
- أوافق طواعية على أن أكون جزءًا من هذه الدراسة البحثية، وأن أتبع إجراءات الدراسة، وأن أقدم المعلومات الضرورية للطبيب أو الممرضات أو أعضاء الفريق الآخرين، حسب الطلب.
- يمكنني بحرية اختيار التوقف عن المشاركة في هذه الدراسة في أي وقت.
- لقد تلقيت نسخة من نموذج معلومات المشارك والموافقة هذا للاحتفاظ بها لنفسي.

اسم المشارك:

رقم هوية المشارك:

توقيع المشارك أو الممثل القانوني:

التاريخ (يوم/شهر/سنة):

اسم الشخص الذي أجرى مناقشة الموافقة:

التاريخ (يوم/شهر/سنة) :

اسم وتوقيع الشاهد :

التاريخ (يوم/شهر/سنة) :

APPENDIX E: Patient Screening Form

MEDICATION MANAGEMENT: PATIENT SCREENING FORM

"I need to ask a few questions to see if you would be eligible for the medication therapy management program. It should take no more than 10 minutes."

#	Question	Response Options	Eligibility Criteria
1	What is your date of birth?	_____ / _____ / _____ (MM/DD/YYYY)	IF 18 OR OLDER: ELIGIBLE IF LESS THAN 18 OR refused OR do not know: INELIGIBLE
2	Has your doctor changed your medication dose or added a new medication within the past month?	☐ YES ☐ NO	If YES, skip to question 6
3	Have you seen a new doctor in the past month?	☐ YES ☐ NO	If YES, skip to question 6
4	Have you been seen in the Emergency Room in the past month?	☐ YES ☐ NO	If YES, skip to question 6
5	Have you been discharged from the hospital in the past month?	☐ YES ☐ NO	If NO to questions 2-5, then INELIGIBLE for the study
6	Have you been told by your doctor that you have any condition that might	☐ YES ☐ NO	

#	Question	Response Options	Eligibility Criteria
	prevent you from completing this 6-month study?		
7	Have you had an interview in the past year where you were asked to bring in all medications and received a list of them?	☐ YES ☐ NO	
8	Do you have any of the following medical problems? (Check all that apply)	☐ Diabetes ☐ Heart Failure ☐ Asthma ☐ Hypertension ☐ Chronic Kidney Disease ☐ Depression ☐ Other: _____	
9	Can you tell me the names of your medications, including over-the-counter medicines, vitamins, or supplements?	**Medication Names:** 1. _____ 2. _____ 3. _____ 4. _____ 5. _____	

Screened by: _____**Date:** _ / __ / ___**Eligibility Determination:** ☐ Eligible ☐ Not Eligible

APPENDIX F: Patient HIV Care and ART Record

PATIENT HIV CARE AND ANTIRETROVIRAL TREATMENT (ART) RECORD

(To be stored in a locked cabinet at the health centre and arranged serially by registration number)

1. PATIENT IDENTIFICATION DATA

Field	Information
Registration Number:	code clinic (2#) - code patient (4#): _____
Name of Treatment Unit:	_____
City:	_____
District:	_____
State/Province:	_____
Name of Patient:	_____
Age:	_____ years
Date of Birth:	_____ / _____ / _____ (dd/mm/yy)
Sex:	☐ Male ☐ Female
Patient's Phone Number:	_____
Address:	_____
City/Village:	_____
District:	_____

Field	Information
State/Province:	_____
Distance from residence to clinic (km):	_____ km
Treatment Supporter's Name:	_____
Treatment Supporter's Address:	_____
Treatment Supporter's Phone:	_____

---

2. HIV DIAGNOSIS AND ENTRY

Field	Information
Date confirmed HIV+ test:	_____ / _____ / _____ (dd/mm/yy)
Place:	_____
Entry point:	☐ 1-VCT ☐ 2-TB ☐ 3-Outpatient ☐ 4-Inpatient ☐ 5-Paediatric ☐ 6-PMTCT ☐ 7-STI ☐ 8-Private ☐ 9-NGO ☐ 10-Self referred ☐ 11-IDU outreach ☐ 12-CSW outreach ☐ 13-Other: _____
Patient transferred in on ART:	☐ Yes ☐ No

Field	Information
Name previous clinic:	_____
Date transferred in:	_____ / _____ / _____ (dd/mm/yy)

---

3. PERSONAL HISTORY

Field	Information
Mode of HIV transmission:	☐ 1 Commercial sex worker (CSW) ☐ 2 Other heterosexual route ☐ 3 Men having sex with men (MSM) ☐ 4 Injecting drug use (IDU) ☐ 5 Blood transfusion ☐ 6 Mother to child ☐ 7 Unknown
For IDUs Substitution therapy:	☐ Yes ☐ No If yes, type: _____
Literate:	☐ Yes ☐ No
Employed:	☐ Yes ☐ No
Alcoholism:	☐ Habitual ☐ Social ☐ No use
Marital status:	☐ Single ☐ Married ☐ Divorced/Separate ☐ Widowed

Field	Information
Estimated monthly household income:	_____

---

4. FAMILY HISTORY

Family Member	Age/Sex	HIV (+/-/unknown)	ART (Y/N)	Registration No. if in care
Partner				
Child 1				
Child 2				
Child 3				

---

5. ANTIRETROVIRAL TREATMENT HISTORY

Question	Response
Was ART received before?	☐ Yes ☐ No
If yes:	☐ PMTCT ☐ Earlier ART
Place:	☐ Private ☐ Govt
Drugs and duration:	_____

---

6. CLINICAL AND LABORATORY INVESTIGATIONS

Visit	Date (dd/mm/yy)	WHO stage	Weight (kg)	Height (cm)	Performance*	Total lymphocyte count	CD4 count
At 1st visit in clinic							
At ART medical eligibility							
At start of ART							
At 6 months ART							
At 12 months ART							
At 24 months ART							

**Performance scale:* A- Normal activity; B- bedridden <50% of the day during last month; C- bedridden >50% of the day during last month*

---

7. ANTIRETROVIRAL TREATMENT

Treatment Started	Date	Substitution, Switch or Stop	Reason (code)	Date Restart	New Regimen
☐ D4T30+3TC+NVP					
☐ D4T40+3TC+NVP					
☐ D4T30+3TC+EFV					
☐ D4T40+3TC+EFV					
☐ ZDV+3TC+NVP					
☐ ZDV+3TC+EFV					

Reasons SUBSTITUTE: 1 toxicity side effects, 2 pregnancy, 3 risk of pregnancy, 4 newly diagnosed TB, 5 new drug available, 6 drug out of stock, 7 other reason

Reasons for SWITCH: 1 clinical treatment failure, 2 immunological failure, 3 virologic failure

Reasons STOP: 1 toxicity side effects, 2 pregnancy, 3 treatment failure, 4 poor adherence, 5 illness hospitalization, 6 drug out of stock, 7 patient lack of finance, 8 patient decision, 9 planned treatment interruption, 10 others

---

8. TUBERCULOSIS TREATMENT DURING HIV

Field	Information
Disease class:	☐ Pulmonary TB Smear-positive ☐ Pulmonary TB Smear-negative ☐ Extrapulmonary site: _____
TB Regimen:	☐ Category I ☐ Category II ☐ Other: _____
Date start TB Rx:	_____ / _____ / _____ (dd/mm/yy)
District:	_____
Health Centre:	_____
TB number:	_____
Treatment outcome:	☐ Cure ☐ Rx completed ☐ Rx failure ☐ Died ☐ Default ☐ Transfer out
Date:	_____ / _____ / _____ (dd/mm/yy)

9. END OF FOLLOW-UP

Outcome	Date
☐ Death	Date of death: _____ / _____ / _____ (dd/mm/yy)
☐ Lost to follow-up (>3 months)	Date last visit: _____ / _____ / _____ (dd/mm/yy)
☐ Transferred out	Date: _____ / _____ / _____ (dd/mm/yy) New clinic: _____

APPENDIX G: Antiretroviral Drug Dispensing Register

ANTIRETROVIRAL DRUG DISPENSING REGISTER

(Maintain a separate page for each day)

Date: _____ / _____ / _____

Reg. No.	Patient's Name	Douvir	Zidolam N	Atripla	Tenolam	EFV600	EFV200	Nevirapine 200	Kaletra	Other specify	Patient's Signatur	Drug Regimen
1												
2												
3												

Drug Regimen					
Patient's Signatur					
Other specify					
Kaletra					
Nevirapine 200					
EFV200					
EFV600					
Tenolam					
Atripla					
Zidolam N					
Douvir					
Patient's Name					
Reg. No.	4	5	6	7	8

Drug Regimen					
Patient's Signatur					
Other specify					
Kaletra					
Nevirapine 200					
EFV200					
EFV600					
Tenolam					
Atripla					
Zidolam N					
Douvir					
Patient's Name					
Reg. No.	9	10	11	12	13

Drug Regimen	Patient's Signatur	Other specify	Kaletra	Nevirapine 200	EFV200	EFV600	Tenolam	Atripla	Zidolam N	Douvir	Patient's Name	Reg. No.	14	15	**Total Tablets**

Signature of the pharmacist/drug dispenser: _____

APPENDIX H: MTM Patient Chart Template

MTM PATIENT CHART TEMPLATE

Patient Name: _____

Patient ID: _____

Date of Birth: _____ / _____ / _____

Age: _____ years

Gender: ☐ Male ☐ Female

Phone Number: _____

Primary Language: ☐ Arabic ☐ English

ALLERGIES

Drug Allergen	Reaction	Severity

MEDICAL HISTORY

Condition	Date Diagnosed	Status	Notes
HIV/AIDS			
Hypertension			
Diabetes			
Chronic Kidney Disease			
Hepatitis B/C			
Tuberculosis			
Depression			
Other: _____			
Other: _____			

CURRENT MEDICATIONS

Medication	Dose	Frequency	Route	Indication	Start Date	Prescriber
1.						
2.						
3.						

Medication	Dose	Frequency	Route	Indication	Start Date	Prescriber
4.						
5.						
6.						
7.						
8.						

LABORATORY RESULTS (Most Recent)

Test	Result	Date	Normal Range
CD4 Count			
Viral Load			<200 copies/mL
Creatinine			
ALT/AST			
Hemoglobin			
Blood Glucose			
Blood Pressure			

MTM VISIT NOTES

Visit Date	Provider	Problems Identified	Interventions	Follow-up

APPENDIX I: MTM Personal Medication List

MTM PERSONAL MEDICATION LIST

Patient Name: _____

Date of Birth: _____ / _____ / _____

Date Form Updated: _____ / _____ / _____

Allergies: _____

Start Date	Stop Date	Medication Name	Tablet Strength	How to Use / When to Use	What It's For

---

Pharmacy Name: _____

Pharmacy Phone: _____

Refill Dates:

1. _____ / _____ / _____
2. _____ / _____ / _____
3. _____ / _____ / _____

IMPORTANT:

- Keep this list with you at all times
- Share it with your doctor, pharmacist, or any healthcare provider
- Update it whenever your medications change
- Bring this list to all medical appointments

APPENDIX J: Modified PCNE Drug Assessment Form

MODIFIED PCNE DRUG ASSESSMENT FORM

Patient Name: _____

Patient ID: _____

Date: _____ / _____ / _____

Visit Number: ☐ Visit 1 ☐ Visit 2 ☐ Follow-up

MTM Provider: _____

SECTION 1: IDENTIFICATION OF DRUG-RELATED PROBLEMS

For each medication the patient is receiving, assess each of the following DRPs. Mark all that apply.

Problem Category	Specific Problem	Medication(s) Involved	Check if Present
Treatment Effectiveness	No effect of drug treatment		☐

Problem Category	Specific Problem	Medication(s) Involved	Check if Present
	Effect of drug treatment not optimal		☐
	Wrong effect of drug treatment		☐
	Untreated indication		☐
Adverse Reactions	Non-allergic adverse reaction		☐
	Allergic reaction		☐
	Toxic reaction		☐
Treatment Costs	Drug treatment more costly than necessary		☐
	Unnecessary drug therapy		☐
Other	Patient dissatisfied with therapy		☐
	Insufficient awareness of health and diseases		☐
	Others (specify): _____		☐

APPENDIX J: Modified PCNE Drug Assessment Form

MODIFIED PCNE DRUG ASSESSMENT FORM

Patient Name: _____

Patient ID: _____

Date: _____ / _____ / _____

Visit Number: ☐ Visit 1 ☐ Visit 2 ☐ Follow-up

MTM Provider: _____

SECTION 1: IDENTIFICATION OF DRUG-RELATED PROBLEMS

For each medication the patient is receiving, assess each of the following DRPs. Mark all that apply.

Problem Category	Specific Problem	Medication(s) Involved	Check if Present
Treatment Effectiveness	No effect of drug treatment		☐
	Effect of drug treatment not optimal		☐
	Wrong effect of drug treatment		☐
	Untreated indication		☐

Problem Category	Specific Problem	Medication(s) Involved	Check if Present
Adverse Reactions	Non-allergic adverse reaction		☐
	Allergic reaction		☐
	Toxic reaction		☐
Treatment Costs	Drug treatment more costly than necessary		☐
	Unnecessary drug therapy		☐
Other	Patient dissatisfied with therapy		☐
	Insufficient awareness of health and diseases		☐
	Others (specify): _____		☐

SECTION 2: CAUSES OF DRUG-RELATED PROBLEMS

One problem can have more than one cause. Write cause codes in boxes below.

Cause Domain	Cause Code	Description
Drug/Dose Selection	C1.1	Inappropriate drug selection

Cause Domain	Cause Code	Description
	C1.2	Inappropriate dosage form
	C1.3	Dosage too high
	C1.4	Dosage too low
	C1.5	No or incomplete drug treatment
	C1.6	Too many drugs prescribed for indication
Drug Use Process	C2.1	Inappropriate timing of administration
	C2.2	Drug underused/overused
	C2.3	Patient unable to use drug as directed
	C2.4	Drug not taken at all
Information	C3.1	Instructions for use not known
	C3.2	Patient unable to understand instructions
	C3.3	Language barrier
Patient/Psychological	C4.1	Patient forgets to take drug
	C4.2	Patient concerns about drug
	C4.3	Patient suspects ineffective drug

Cause Domain	Cause Code	Description
	C4.4	Patient unwilling to change drug
	C4.5	Patient unwilling to adapt lifestyle
	C4.6	Burden of therapy
Logistics	C5.1	Medication not available
	C5.2	Prescribing error
	C5.3	Dispensing error
	C5.4	Drug supply problem

DRP 1 Cause Codes: ☐ _____ ☐ _____ ☐ _____

DRP 2 Cause Codes: ☐ _____ ☐ _____ ☐ _____

DRP 3 Cause Codes: ☐ _____ ☐ _____ ☐ _____

SECTION 3: INTERVENTIONS

Intervention	Implemented (Y/N)	Date	Notes
Referred to prescriber	☐ Yes ☐ No		
Drug changed	☐ Yes ☐ No		
Dose changed	☐ Yes ☐ No		

Intervention	Implemented (Y/N)	Date	Notes
Formulation changed	☐ Yes ☐ No		
Drug stopped	☐ Yes ☐ No		
New drug started	☐ Yes ☐ No		
Patient education/counseling	☐ Yes ☐ No		
Monitoring initiated	☐ Yes ☐ No		

SECTION 4: OUTCOMES

Outcome	Check if Achieved
Problem solved	☐
Problem partially solved	☐
Problem not solved	☐
No outcome documented	☐

MTM Provider Signature: _____

APPENDIX K: Prescriber Communication Form

PRESCRIBER COMMUNICATION FORM

DATE: _____ / _____ / _____

TO: Dr. _____ (Prescriber Name)

FROM: _____ (MTM Provider Name)

RE: Patient: _____

DOB: _____ / _____ / _____

Patient ID: _____

DRUG-RELATED PROBLEM IDENTIFIED:

RECOMMENDATION(S):

COMMENTS:

SUPPORTING INFORMATION:

☐ Medication list attached
☐ Laboratory results attached
☐ Relevant clinical notes attached
☐ Other documentation attached

PRESCRIBER RESPONSE

☐ **Accept recommendation(s)** – Please implement as suggested

☐ **Do not accept recommendation(s)** – Reason: _____

☐ **Modify** – Please implement the following modified plan:

Prescriber Signature: _____

Date: _____ / _____ / _____

Please fax back
to: _____ **Fax:** _____

APPENDIX L: MTM Provider Interview Tool

MTM PROVIDER INTERVIEW TOOL

Instructions: Start with a formal introduction and brief description of events to take place. Ask patient to display containers for all prescription medications, OTC products, herbal products and nutritional products (if available). If item(s) not available, ask patient to display a list of medication(s). If patient cannot provide either, have patient verbalize list of medications.

(Prompt the patient to try and remember patches, creams, eye drops, inhalers, sample medications, shots, optics, herbals, vitamins, and minerals).

Patient ID: _____ Date: _____ / _____ / _____

Interviewer: _____

---

1. **Do you have any allergies? If so, with what drugs and what was the reaction?**

---

2. **What is your height?** _____ cm
3. **What is your weight?** _____ kg
4. **Does anyone normally help you remember to take your medicines?**
   ☐ Yes ☐ No

If yes, who? (allow that person to assist with answering the questions)

---

5. **What medicines are you taking at the moment (brand/generic)?**

Medication	Dosage	Route	Directions	Condition	Start Date	Last Dose	Forgotten Doses	Time of Day
1.								
2.								
3.								
4.								
5.								

6. **For each medication ask:**
   a. How do you take this medication? _____
   b. What condition does this medication treat? _____
   c. When did you start the medication or how long have you taken this medication?
   _____
   d. When was the last time the dose of this medication was changed?
   _____
   e. How many times in the past 2 weeks have you forgotten a dose of this medication?
   _____
   f. What time of day do you take this medication?
   _____

7. **Do you take anything that you buy without a prescription from a health food store, supermarket, etc?**
   ☐ Yes ☐ No

If yes, repeat questions 5, 6, and 7 for these products.

---

8. **Have you recently stopped any medications? Why?**

---

9. **Has the prescriber changed any medications recently?**

---

10. **Do you have any other conditions for which you are not taking any prescription or non-prescription medications or natural products?**

---

11. **Does the prescriber periodically check labs, blood pressure, etc to monitor your conditions?**
    ☐ Yes ☐ No

If yes, how often? _____
Last date: _____ / _____ / _____
Results (if known): _____

12. **Are you suffering any side effects now?**
    ☐ Yes ☐ No

a. If yes, what side effects? _____
b. Which of your medication(s) do you think is (are) causing the problem(s)?
_____

13. **Do you have any questions or concerns about your medications?**

Interviewer Notes:

APPENDIX M: MTM Provider Time Log

MTM PROVIDER TIME LOG

Provider Name: _____ **Month:** _____

Date	Patient ID	Time Started	Time Ended	Time Elapsed (min)	Activity Type	Notes
					☐ First Patient Visit	
					☐ Second Patient Visit	
					☐ Prescriber Contact	
					☐ DRP Resolution	
					☐ Documentation	
					☐ Other: _____	
					☐ First Patient Visit	

Date	Patient ID	Time Started	Time Ended	Time Elapsed (min)	Activity Type	Notes
					☐ Second Patient Visit	
					☐ Prescriber Contact	
					☐ DRP Resolution	
					☐ Documentation	
					☐ Other: _____	
					☐ First Patient Visit	
					☐ Second Patient Visit	
					☐ Prescriber Contact	
					☐ DRP Resolution	

Date	Patient ID	Time Started	Time Ended	Time Elapsed (min)	Activity Type	Notes
					☐ Documentation ☐ Other: _____ ☐ First Patient Visit ☐ Second Patient Visit ☐ Prescriber Contact ☐ DRP Resolution ☐ Documentation ☐ Other: _____	

MONTHLY SUMMARY

Activity Type	Total Number	Total Time (min)	Average Time (min)
First Patient Visit			
Second Patient Visit			
Prescriber Contact			
DRP Resolution			
Documentation			
Other			
TOTAL			

Provider Signature: _____ **Date:** _____ / _____ / _____

APPENDIX N: Patient Satisfaction Survey

PATIENT SATISFACTION SURVEY

Patient ID: _____ **Date:** _____ / _____ / _____

Instructions: Please rate your satisfaction with the medication therapy management (MTM) services you received. For each statement, circle the number that best represents your opinion.

#	Satisfaction Domain	Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied
1	Overall satisfaction with MTM services	1	2	3	4	5
2	Pharmacist's communication skills	1	2	3	4	5
3	Pharmacist's knowledge about my medications	1	2	3	4	5
4	My understanding of medications after counseling	1	2	3	4	5
5	Privacy during consultations	1	2	3	4	5
6	Respect shown by the pharmacist	1	2	3	4	5
7	Convenience of	1	2	3	4	5

#	Satisfaction Domain	Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied
	appointment scheduling					
8	Time spent during MTM visits	1	2	3	4	5
9	Helpfulness of the personal medication list	1	2	3	4	5
10	Willingness to recommend this service to others	1	2	3	4	5

OVERALL ASSESSMENT

11. **How well did the staff work together to provide your care?**
    ☐ Very Poor ☐ Poor ☐ Fair ☐ Good ☐ Excellent
12. **Overall rating of care received during MTM visits:**
    ☐ Very Poor ☐ Poor ☐ Fair ☐ Good ☐ Excellent
13. **Would you recommend this MTM service to others?**
    ☐ Definitely No ☐ Probably No ☐ Not Sure ☐ Probably Yes ☐ Definitely Yes

---

COMMENTS

What did you like most about the MTM service?

What could be improved?

Any other comments?

Thank you for your participation!

APPENDIX O: Office, Emergency Department, and Hospital Visit Assessment Survey Form

OFFICE, EMERGENCY DEPARTMENT, AND HOSPITAL VISIT ASSESSMENT SURVEY FORM

Patient ID: _____ **Date:** _____ / _____ / _____

Assessment Period: Past 90 days (3 months) ☐ Past 180 days (6 months)

Interviewer: _____

SECTION A: OFFICE VISITS

1. **In the past 90 days, how many times did you visit a doctor's office or clinic?**
   _____ visits
2. **Were any of these visits related to medication side effects or problems?**
   ☐ Yes ☐ No ☐ Unsure

If yes, how many? _____ *visits*

3. **Did you receive any new medications during these visits?**
   ☐ Yes ☐ No

If yes, please list: _____

4. **Were any of your medications changed during these visits?**
   ☐ Yes ☐ No

If yes, please describe: _____

5. **Were you referred to a specialist during any visit?**
   ☐ Yes ☐ No

If yes, what specialty? _____

SECTION B: EMERGENCY DEPARTMENT VISITS

6. **In the past 90 days, how many times did you visit an Emergency Department?**
   _____ visits
7. **Were any of these ED visits related to medication side effects or problems?**
   ☐ Yes ☐ No ☐ Unsure

If yes, how many? _____ visits

8. **For each ED visit, please describe the reason:**

---

9. **Were you admitted to the hospital from any ED visit?**
   ☐ Yes ☐ No

If yes, how many times? _____

SECTION C: HOSPITALIZATIONS

10. **In the past 90 days, how many times were you admitted to the hospital?**
    _____ admissions
11. **Total number of days in hospital:** _____ days
12. **Were any of these hospitalizations related to medication side effects or problems?**
    ☐ Yes ☐ No ☐ Unsure

If yes, how many? _____ admissions

13. **For each hospitalization, please describe the reason:**

SECTION D: MEDICATION CHANGES

14. **Overall, in the past 90 days:**
    - New medications started: _____
    - Medications stopped: _____
    - Dose changes: _____
15. **Do you feel your medications are currently well-managed?**
    ☐ Yes ☐ No ☐ Unsure

Comments: _____

16. **Have you experienced any new side effects from your medications in the past 90 days?**
    ☐ Yes ☐ No

If yes, please describe: _____

Interviewer Notes:

APPENDIX P: Participant's Material Publication Consent Form

PARTICIPANT'S MATERIAL PUBLICATION CONSENT FORM

Research Title: IMPLEMENTATION AND ASSESSMENT OF A MEDICATION THERAPY MANAGEMENT PROGRAM FOR HIV PATIENT AT HIGH RISK OF ADVERSE DRUG EVENTS IN KHARTOUM SUDAN

Researcher's Name: NADA ABDELRAHMAN MOHAMED IBRAHIM (P-IPD0025/21(R))

To become a part of this study, you or your legal representative must sign this page.

By signing this page, I am confirming the following:

- I understand that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalists worldwide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors worldwide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
    - The materials will not be used as advertisement purposes nor as packaging materials.
    - The materials will not be used out of context - i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

Participant Name: _____

Participant I.C No.: _____

Signature of Participant: _____

Date (dd/MM/yy): _____ / _____ / _____

Name and Signature of Individual Conducting Consent Discussion: _____

Date (dd/MM/yy): _____ / _____ / _____

Note: All participants who are involved in this study will not be covered by insurance.

APPENDIX Q: Pharmacist Consent Form

CONSENT FORM FOR PHARMACISTS

Research Title: Implementation and Assessment of a Medication Therapy Management Program for HIV Patients at High Risk of Adverse Drug Events in Khartoum, Sudan

Principal Investigator: Nada Abdelrahman Mohamed Ibrahim

Co-Investigators: Dr. Hasni bin Arsad (Main Supervisor), Dr. Mohd Yusmaidie bin Aziz (Co-Supervisor), Dr Christina Malini Christopher

---

1. PURPOSE

You are invited to participate as a provider in a study assessing the impact of pharmacist-led MTM services on HIV patient outcomes. This research will help improve medication safety programs in Sudan.

---

2. WHAT'S INVOLVED

As an MTM provider, you will be asked to:

- Deliver MTM services per study protocol (2-4 sessions per patient over 6 months)
- Document interventions using standardized forms

- Participate in a 30-45 minute interview about your experiences (optional)

---

3. RISKS & BENEFITS

Potential Risks:

- Time burden (1-2 hours per month for documentation)
- Emotional discomfort when discussing challenging cases

Potential Benefits:

- Continuing Professional Development (CPD) credits
- Contribution to evidence-based HIV care in Sudan
- Certificate of Research Participation for your portfolio

---

4. PRIVACY PROTECTIONS

- Your name will not be linked to patient outcomes in reports
- Interview recordings (if applicable) will use codes (e.g., "PHARM-01")
- Data stored on password-protected servers at Universiti Sains Malaysia

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5. VOLUNTARY PARTICIPATION

- You may withdraw from the study at any time without penalty
- Refusal will not affect your employment or professional standing

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6. CONTACT INFORMATION

For questions, contact:

Dr. Nada Ibrahim
Phone: +249 90 624 0182
Email: nadaaboras@yahoo.com

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM

Phone: 09-767 2354 / 09-767 2362
Email: bazlan@usm.my

SIGNATURE SECTION

By signing below, I confirm that:

1. I understand the study purpose and procedures
2. My questions have been answered
3. I voluntarily agree to participate

Pharmacist Name: _____

License #: _____

Signature: _____

Date: _____ / _____ / _____

Researcher Name: _____

Signature: _____

Date: _____ / _____ / _____

Witness Name: _____

Signature: _____

Date: _____ / _____ / _____

VERBAL CONSENT ADDENDUM (if needed)

"I confirm that this form was explained verbally, and I agree to participate."

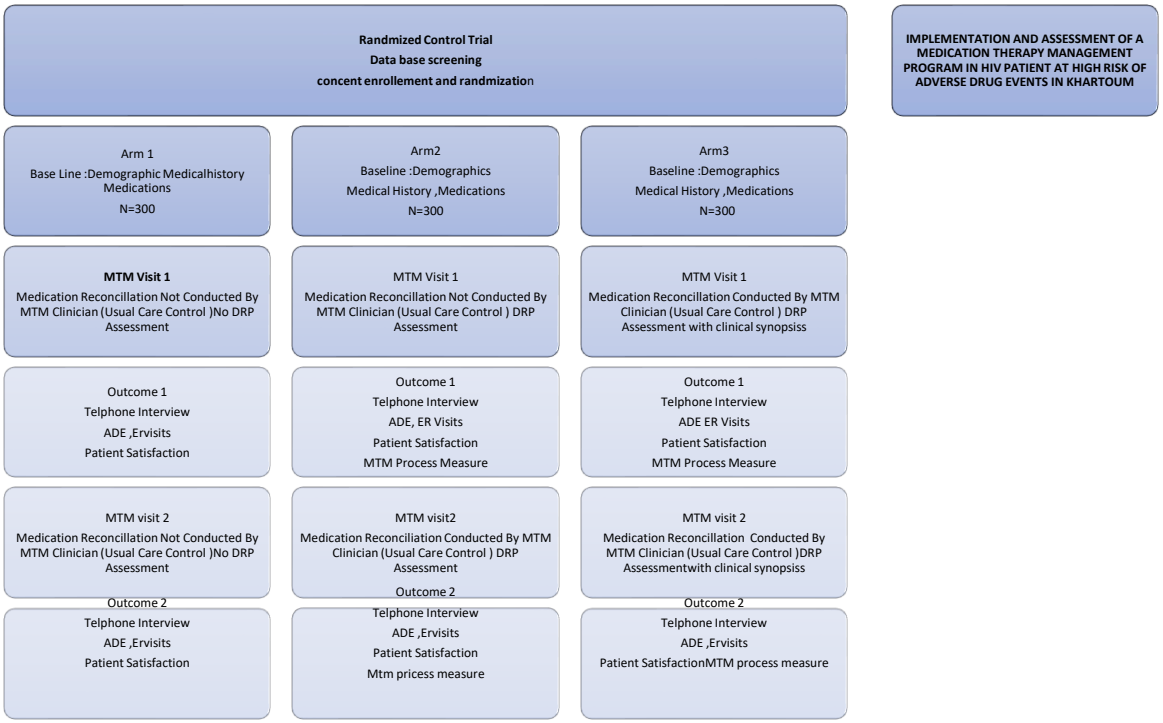
Witness Name (Clinic Director/Supervisor): _____

Signature: _____

Date: _____ / _____ / _____

APPENDIX R: Study Flowchart

STUDY FLOWCHART: HIV MTM RANDOMIZED CONTROLLED TRIAL



The flow chart outlines a randomized controlled trial (RCT) with three arms: Arm 1 (Usual Care), Arm 2 (Baseline Demographics), and Arm 3 (Baseline Demographics). Each arm progresses through a series of steps, with the first step being the MTM Visit 1, where a medication reconciliation is conducted by an MTM Clinician.

For Arm 1, the medication reconciliation will not be conducted, and the patient receives usual care control. For Arms 2 and 3, the medication reconciliation will be conducted, and the patients receive usual care control or are assessed with clinical information.

After MTM Visit 1, the study progresses to Outcome 1, which will involve a telephone interview assessing adverse drug events (ADE), emergency room (ER) visits, and patient satisfaction. This will be followed by MTM Visit 2, where another medication reconciliation is conducted.

Finally, the study will conclude with Outcome 2, which is another telephone interview assessing ADE, ER visits, patient satisfaction, and MTM process measures.

APPENDIX S: Data Collection Instruments Summary

DATA COLLECTION INSTRUMENTS SUMMARY

#	Instrument	Purpose	Administered By	Timing	Format
1	Patient Screening Form	Determine eligibility	Research Assistant	Enrollment	Interview
2	Patient HIV Care and ART Record	Document clinical history	Clinic Staff	Baseline	Chart Review
3	Antiretroviral Drug Dispensing Register	Track medication dispensing	Pharmacist	Ongoing	Log
4	MTM Patient Chart Template	Collect clinical data for MTM	Pharmacist	Each MTM Visit	Chart Review

#	Instrument	Purpose	Administered By	Timing	Format
5	MTM Personal Medication List	Provide patient with medication record	Pharmacist	Initial MTM Visit	Patient Copy
6	Modified PCNE Drug Assessment Form	Identify and classify DRPs	Pharmacist	Each MTM Visit	Checklist
7	Prescriber Communication Form	Communicate with physicians	Pharmacist	As needed	Fax/Email
8	MTM Provider Interview Tool	Assess patient medication use	Pharmacist	Each MTM Visit	Interview
9	MTM Provider Time Log	Track time spent on MTM activities	Pharmacist	Ongoing	Log
10	Patient Satisfaction Survey	Assess patient satisfaction	Research Assistant	3 and 6 months	Interview
11	Office, ED, Hospital Visit Assessment	Track healthcare utilization	Research Assistant	3 and 6 months	Interview

#	Instrument	Purpose	Administered By	Timing	Format
12	Participant Information Sheet (English)	Inform participants about study	Research Assistant	Enrollment	Document
13	Participant Information Sheet (Arabic)	Inform participants about study	Research Assistant	Enrollment	Document
14	Informed Consent Form (English)	Document participant consent	Research Assistant	Enrollment	Document
15	Informed Consent Form (Arabic)	Document participant consent	Research Assistant	Enrollment	Document
16	Participant Material Publication Consent	Consent for publication of materials	Research Assistant	Enrollment	Document
17	Pharmacist Consent Form	Document pharmacist consent	PI	Before training	Document
18	Study Flowchart	Visualize study procedures	N/A	N/A	Diagram

DATA COLLECTION SCHEDULE

Instrument	Baseline	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Patient Screening Form	✓						
Informed Consent	✓						
Patient HIV Care and ART Record	✓						
MTM Patient Chart Template	✓	✓		✓			✓
MTM Provider Interview Tool	✓	✓		✓			✓
Modified PCNE Drug Assessment Form	✓	✓		✓			✓
MTM Personal Medication List	✓			✓			✓

Instrument	Baseline	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Prescriber Communication Form		As needed	As needed	As needed	As needed	As needed	As needed
MTM Provider Time Log	✓	✓	✓	✓	✓	✓	✓
Patient Satisfaction Survey				✓			✓
Office, ED, Hospital Visit Assessment				✓			✓