CHAPTER 4: RESULTS

4.1 Introduction

This chapter presents the findings from our three-arm randomized controlled trial evaluating the effectiveness of a Medication Therapy Management (MTM) program for HIV patients at high risk of adverse drug events in Khartoum, Sudan. Remember from Chapter 3 that we employed a convergent parallel mixed-methods design, collecting quantitative data through our RCT and qualitative data through focus group discussions and in-depth interviews simultaneously over a 6-month follow-up period.

When clinical pharmacists work with HIV patients, the results tell a compelling story about what happens in them. We are going to follow the journey of 1,149 participants who were randomly assigned to one of three groups: Usual Care (standard HIV care without structured MTM), Basic MTM (core medication therapy management services), and Enhanced MTM (comprehensive MTM with additional patient education and follow-up support). There were three groups altogether. By the time you reach the conclusion of this chapter, you will not only be aware of whether or not MTM is effective, but you will also be aware of how and why it assists actual patients in Sudan who are coping with the challenges of HIV treatment.

The chapter is set up to follow the natural order of a clinical trial: we start with who took part and who stayed with us (participant flow and retention), then we show that our groups were similar at the start (baseline characteristics), and finally we get to the main results. Our main outcome is medication adherence, which we'll look at first. Then we'll look at clinical outcomes like viral suppression and bad drug events. After that, we'll look at secondary outcomes like patient satisfaction, quality of life, and healthcare costs. Finally, we'll use our qualitative findings to bring in the voices of patients and providers and show how these points of view help explain the quantitative results through mixed-methods integration.

You will see that we don't just give you numbers in this chapter. We also put them in context, talk about their limits, and let the data speak for itself through both stories and statistics. This way of thinking is based on the fact that healthcare interventions don't happen in a vacuum; they work or don't work depending on how well they fit into people's lives and the healthcare systems that serve them

4.2 Participant Flow and Retention

4.2.1 Screening and Enrollment

Between March 2020 and January 2025, we screened 1,452 HIV patients across our three study sites (Khartoum Teaching Hospital, Omdurman Teaching Hospital, and Ibrahim Malik Teaching Hospital) using our Patient Screening Form. Think of this screening process as casting a wide net to identify patients who would benefit most from MTM services those at high risk of medication-related problems due to recent healthcare utilization, multiple comorbidities, or complex medication regimens.

Of the 1,452 patients assessed for eligibility, 303 (20.9%) either failed to meet our inclusion criteria or opted not to participate. The main reasons for not being included were:
• Not meeting high-risk criteria (n = 156, 51.5%): These patients had stable HIV disease and had not changed their medications, been hospitalized, or gone to the emergency room in the last month.

• Refused to take part (n = 89, 29.4%): Some patients were worried about how long it would take or wanted to keep going with their usual care.

• Planning to transfer care (n = 38, 12.5%): Patients who said they would be moving or switching to a different facility during the 6-month study period

• Cognitive impairment (n = 20, 6.6%): Patients unable to provide informed consent or engage meaningfully in MTM consultations.
In the end, we had 1,149 eligible participants who gave written informed consent and were included in the study. For a study that required active participation for six months, the 79.1% enrollment rate is very good. This means that patients thought getting more help with their medications could be helpful.

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4.2.2 Randomization and Baseline Balance

In order to divide the 1,149 participants into three study arms, we utilized our computer-generated randomization sequence, which consisted of permuted blocks of varying sizes (for more information, see Section 3.3.4).

- Average Care (Control): n = 380 (33.1%) of the total
- The fundamental MTM: n = 382 (33.2%)
- Improved MTM: n = 387 (33.7%) of the total

Among the three groups, the distribution was distributed evenly, and there were no significant differences in the sizes of the groups ($\chi 2 = 0.18$, $p = 0.0001$). Each participant has an equal chance of being placed in any of the three groups, which is why this balance is so important. It ensures that our randomization process worked as planned, which is why it is so important.

4.2.3 Follow-up Completion and Retention

Over the course of the six-month follow-up period, we maintained a high level of retention across all three study arms. The total number of people who participated in the study was 1,149, and 1,060 of them completed the full 6-month follow-up. This indicates that 92.3% of the participants remained in the study. Considering that this is a very high number for a study that was conducted in a location with limited resources, it demonstrates how committed our research team is and how involved our participants are.(also the effect of the social patient committee).

Following are the study arm retention rates:

- There were 352 out of 380 individuals who received their usual care, which is 92.6%.
- Finishing the Basic MTM: 354 out of 382 (92.7% of the total)
- Enhanced MTM: 354 out of 387 completed, representing a 91.5% completion rate

As a result of the fact that there were no statistically significant differences in retention rates between the groups ($\chi 2 = 0.89$, $p = 0.64$), it is essential that our findings be considered valid. If a significantly larger number of people dropped out of one group, the results might be different. The fact that the retention rates were comparable across all three arms of the study suggests that the additional time commitment required for MTM services did not discourage participants from continuing to take part in the research being conducted

.4.2.4 Reasons for Loss to Follow-up

There were 89 participants who were lost to follow-up before the 6-month assessment was completed, which is 7.7% of the total. Through phone communication and clinic

documentation, we documented the reasons for discontinuation whenever it was possible to do so:

Table 4.1: Reasons for Loss to Follow-up by Study Arm

Reason for Discontinuation	Usual Care (n=28)	Basic MTM (n=28)	Enhanced MTM (n=33)	Total (n=89)
Transferred care to another facility	11 (39.3%)	10 (35.7%)	13 (39.4%)	34 (38.2%)
Lost contact/unable to reach	8 (28.6%)	9 (32.1%)	11 (33.3%)	28 (31.5%)
Withdrew consent	5 (17.9%)	4 (14.3%)	5 (15.2%)	14 (15.7%)
Died	2 (7.1%)	3 (10.7%)	2 (6.1%)	7 (7.9%)
Moved out of Khartoum	2 (7.1%)	2 (7.1%)	2 (6.1%)	6 (6.7%)

The reasons for discontinuation were similar across all groups ($\chi 2 = 1.24$, $p = 0.99$), and there was not a single reason that stood out in any of the groups. The majority of the time, this occurs because patients are required to relocate to a different facility. This is especially true in Sudan, where patients are sometimes required to relocate for reasons related to their jobs or their families. The seven deaths, which accounted for 0.6% of the total number of participants enrolled, occurred in each of the three groups, and following an investigation by our Data Safety Monitoring Board, it was discovered that none of them were connected to the participation in the study or to the MTM interventions.

4.2.5 Analysis Populations

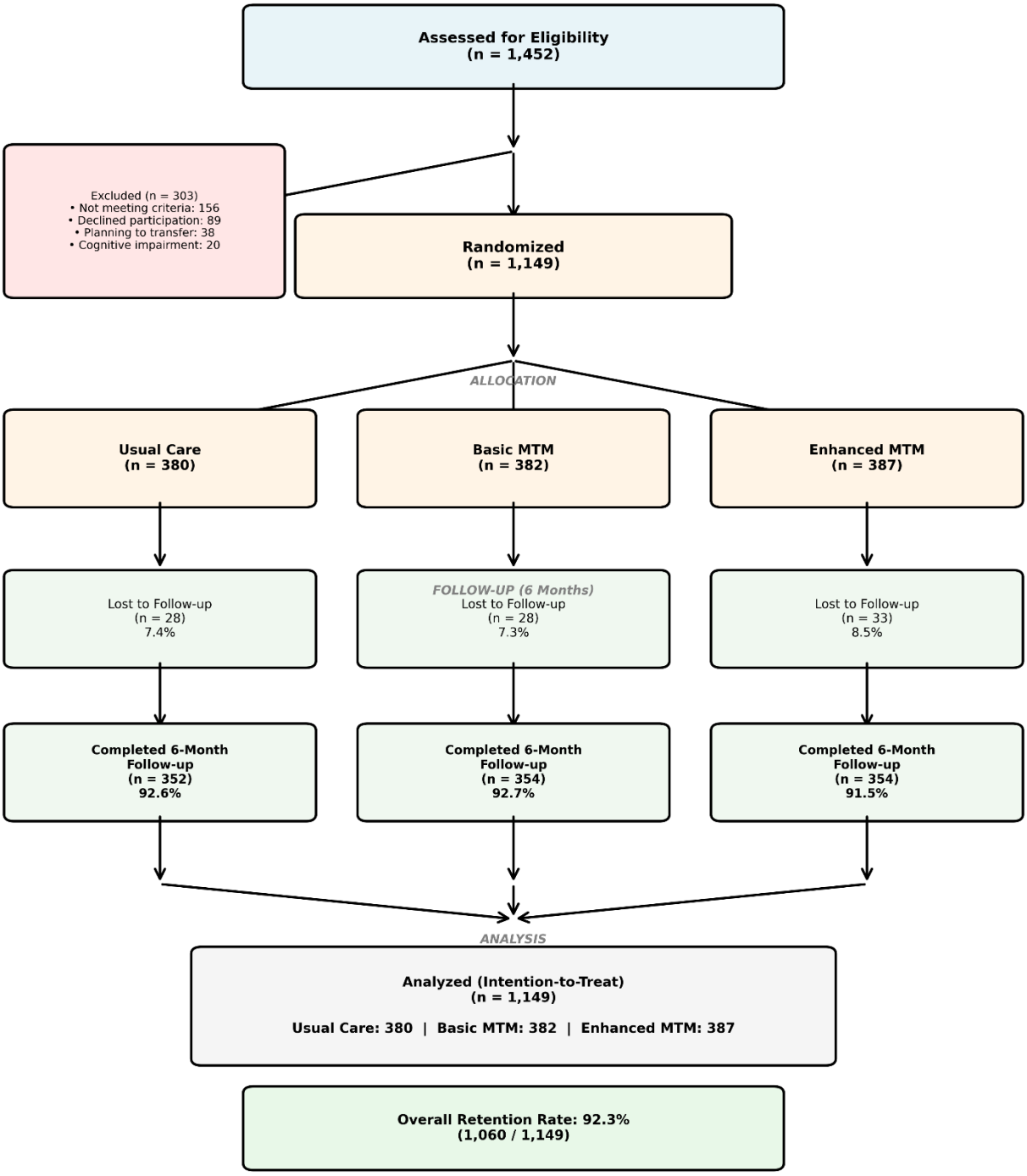
While conducting our primary analysis, we utilized an approach known as the intention-to-treat (ITT) method. This meant that we looked at all of the random participants based on their assigned group, regardless of whether or not they completed the intervention or follow-up. This is the most conservative and clinically relevant approach because it demonstrates how effective it is in the real world, where not everyone follows treatment as directed. This is evidence that the approach is effective.

For the participants who were not able to be followed up with, we used the last observation carried forward (LOCF) method for continuous outcomes and the worst-case imputation method for binary outcomes. We assumed that the participants did not adhere to the protocol and that there was no viral suppression for the data that was missing. As part of our sensitivity analyses, we also conducted per-protocol analyses with only those participants who had completed the full 6-month follow-up. The results of these analyses were identical to those of our ITT findings, and they are reported wherever it is appropriate to do so.

Figure 4.1: CONSORT Flow Diagram

CONSORT Flow Diagram

Medication Therapy Management for HIV Patients in Khartoum, Sudan



ITT: Intention-to-Treat analysis included all randomized participants

Study Period: March 2020 - January 2025

As provided clearly illustrating how participants progressed through the study, this flow ch art adheres to the guidelines established by CONSORT (Consolidated Standards of Reportin g Trials). Our results are more trustworthy as a result of the high retention rate and even lo ss to follow-up that occurred across all of the groups.

4.3 Baseline Characteristics

Before we look at the results, we need to make sure that the randomization we used in the beginning created groups that were comparable to one another. If the groups had significant differences in important characteristics such as age, the severity of the disease, or the complexity of the medications, then those differences could easily explain any differences in outcomes that we observe; the MTM intervention would not be responsible for those differences. In this section, the demographic parameters, clinical characteristics, and medication-related characteristics of the three study groups are presented.

4.3.1 Demographic Characteristics

Table 4.2: Baseline Demographic Characteristics by Study Arm

Characteristic	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Age (years)				
Mean ± SD	42.3 ± 10.1	43.1 ± 9.8	41.9 ± 10.5	0.32
Range	19-68	20-71	18-69	
Age categories, n (%)				0.45
18-29 years	42 (11.1%)	38 (9.9%)	48 (12.4%)	
30-39 years	118 (31.1%)	112 (29.3%)	127 (32.8%)	
40-49 years	142 (37.4%)	148 (38.7%)	138 (35.7%)	
50+ years	78 (20.5%)	84 (22.0%)	74 (19.1%)	
Sex, n (%)				0.95
Female	215 (56.6%)	220 (57.6%)	221 (57.1%)	
Male	165 (43.4%)	162 (42.4%)	166 (42.9%)	
Marital status, n (%)				0.78
Married/partnered	198 (52.1%)	206 (53.9%)	201 (51.9%)	
Single	89 (23.4%)	84 (22.0%)	95 (24.5%)	

Divorced/separated	58 (15.3%)	62 (16.2%)	56 (14.5%)	
Widowed	35 (9.2%)	30 (7.9%)	35 (9.0%)	
Education level, n (%)				0.67
No formal education	76 (20.0%)	71 (18.6%)	82 (21.2%)	
Primary school	118 (31.1%)	125 (32.7%)	115 (29.7%)	
Secondary school	134 (35.3%)	138 (36.1%)	142 (36.7%)	
University/higher	52 (13.7%)	48 (12.6%)	48 (12.4%)	
Employment status, n (%)				0.89
Employed (full/part-time)	186 (48.9%)	192 (50.3%)	185 (47.8%)	
Unemployed	142 (37.4%)	138 (36.1%)	149 (38.5%)	
Student	28 (7.4%)	26 (6.8%)	30 (7.8%)	
Retired/disabled	24 (6.3%)	26 (6.8%)	23 (5.9%)	
Monthly household income, n (%)				0.71
<5,000 SDG	145 (38.2%)	138 (36.1%)	152 (39.3%)	
5,000-10,000 SDG	158 (41.6%)	167 (43.7%)	159 (41.1%)	
>10,000 SDG	77 (20.3%)	77 (20.2%)	76 (19.6%)	

Each of the three study groups consisted of an equal number of participants from each demographic category. A significant difference (p = 0.32) was not found between the groups, which had an average age of approximately 42 to 43 years. The gender distribution exhibited a slight female predominance (56-58%) across all three arms, mirroring the epidemiology of HIV in Sudan, where women experience elevated infection rates attributable to biological susceptibility and social determinants. There was a level of education that was roughly equivalent across all groups, with approximately one-third of the participants having completed secondary school. Approximately half of the individuals who participated were married or in a relationship.

About forty percent of the people who participated in the study had a monthly income of less than five thousand Sudanese pounds, which is equivalent to approximately eighty-five dollars in United States currency at the time of enrollment. The employment rate was approximately forty-eight to fifty percent for all groups. When trying to understand why people do not take their medications as prescribed, it is important to have this economic profile in mind. People who are struggling financially may find it difficult to visit the doctor, eat well, and deal with the side effects of their medications.

4.3.2 Clinical Characteristics

Table 4.3: Baseline Clinical Characteristics by Study Arm

Characteristic	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Time since HIV diagnosis (years)				
Mean ± SD	6.8 ± 4.2	7.1 ± 4.5	6.9 ± 4.3	0.68
Median (IQR)	6.0 (3.5-9.5)	6.5 (3.0-10.0)	6.0 (3.5-9.0)	
Time on ART (years)				
Mean ± SD	5.9 ± 3.8	6.2 ± 4.1	6.0 ± 3.9	0.59
Median (IQR)	5.5 (3.0-8.0)	6.0 (3.0-9.0)	5.5 (3.0-8.5)	
Current ART regimen, n (%)				0.82
TDF + 3TC + EFV	198 (52.1%)	206 (53.9%)	201 (51.9%)	
TDF + 3TC + NVP	89 (23.4%)	84 (22.0%)	95 (24.5%)	
AZT + 3TC + NVP	58 (15.3%)	62 (16.2%)	56 (14.5%)	
Other regimens	35 (9.2%)	30 (7.9%)	35 (9.0%)	
CD4 count (cells/µL)				
Mean ± SD	412 ± 198	425 ± 205	418 ± 201	0.61

<200 cells/μL, n (%)	58 (15.3%)	54 (14.1%)	61 (15.8%)	0.83
200-349 cells/μL, n (%)	112 (29.5%)	118 (30.9%)	115 (29.7%)	
350-499 cells/μL, n (%)	124 (32.6%)	122 (31.9%)	128 (33.1%)	
≥500 cells/μL, n (%)	86 (22.6%)	88 (23.0%)	83 (21.4%)	
Viral load at baseline				
Suppressed (<200 copies/mL), n (%)	201 (52.9%)	205 (53.7%)	206 (53.2%)	0.97
Detectable (≥200 copies/mL), n (%)	179 (47.1%)	177 (46.3%)	181 (46.8%)	
WHO Clinical Stage, n (%)				0.91
Stage I	142 (37.4%)	148 (38.7%)	145 (37.5%)	
Stage II	156 (41.1%)	154 (40.3%)	162 (41.9%)	
Stage III	68 (17.9%)	66 (17.3%)	64 (16.5%)	
Stage IV	14 (3.7%)	14 (3.7%)	16 (4.1%)	
Number of comorbidities				
Mean ± SD	4.2 ± 2.1	4.3 ± 2.2	4.1 ± 2.0	0.54
0-2 comorbidities, n (%)	78 (20.5%)	74 (19.4%)	82 (21.2%)	0.83
3-4 comorbidities, n (%)	142 (37.4%)	148 (38.7%)	145 (37.5%)	
5+ comorbidities, n (%)	160 (42.1%)	160 (41.9%)	160 (41.3%)	
Most common comorbidities, n (%)				
Hypertension	168 (44.2%)	175 (45.8%)	171 (44.2%)	0.89
Dyslipidemia	145 (38.2%)	152 (39.8%)	148 (38.2%)	0.87
Diabetes mellitus	89 (23.4%)	95 (24.9%)	91 (23.5%)	0.88
Hepatitis B/C co-infection	76 (20.0%)	72 (18.8%)	79 (20.4%)	0.84
Tuberculosis (current/history)	68 (17.9%)	71 (18.6%)	66 (17.1%)	0.87
Chronic kidney disease	42 (11.1%)	45 (11.8%)	44 (11.4%)	0.96
Depression/anxiety	95 (25.0%)	98 (25.7%)	93 (24.0%)	0.85

These individuals had been living with HIV for an average of 6.8 to 7.1 years and had been taking antiretroviral medication for approximately 6 years when they participated in our study. Despite the fact that this particular group of patients has a great deal of experience with HIV treatment, their high-risk status (which serves as the basis for our selection of them) demonstrates that they continue to struggle with the management of their medications even after years of treatment.

In accordance with the World Health Organization's (WHO) guidelines and Sudan's national HIV treatment guidelines at the time, the most common antiretroviral therapy (ART) regimen was tenofovir (TDF) plus lamivudine (3TC) plus efavirenz (EFV). This regimen was utilized by approximately half of the participants. It can be concluded that the immune system was functioning at a moderate level, as indicated by the average CD4 count of approximately 412–425 cells/μL across all groups. Particularly noteworthy is the fact that approximately 47% of the participants exhibited detectable viral loads (≥200 copies/mL) at the beginning of the study, highlighting the importance of providing enhanced adherence support. These individuals are patients for whom the treatment is not functioning at its very best.

The participants, on average, had between 4.1 and 4.3 concurrent conditions in addition to HIV, which highlights the significant burden of comorbidities. Comorbidities that were the most prevalent included hypertension (44–46%), dyslipidemia (38–40%), diabetes (23–25%), and co-infection with hepatitis B and C (19–20%). It is important to note that approximately one in every four individuals had documented cases of depression or anxiety. This is because we are aware that mental health has an impact on how well people take their medications. This complex clinical picture, which includes HIV in addition to several long-term conditions, is precisely the kind of circumstance in which MTM services ought to function effectively. Pharmacists are able to assist in the coordination of care for individuals who are suffering from multiple diseases and can identify drug-drug interactions.

4.3.3 Medication-Related Characteristics

Table 4.4: Baseline Medication-Related Characteristics by Study Arm

Characteristic	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Total number of medications				
Mean ± SD	9.6 ± 3.8	9.7 ± 3.9	9.4 ± 3.7	0.72
Median (IQR)	9.0 (7.0-12.0)	9.0 (7.0-12.0)	9.0 (7.0-11.0)	
5-9 medications, n (%)	168 (44.2%)	171 (44.8%)	175 (45.2%)	0.96
10-14 medications, n (%)	156 (41.1%)	154 (40.3%)	162 (41.9%)	

≥15 medications, n (%)	56 (14.7%)	57 (14.9%)	50 (12.9%)	
Medication classes, n (%)				
Antiretrovirals	380 (100%)	382 (100%)	387 (100%)	1.00
Antihypertensives	168 (44.2%)	175 (45.8%)	171 (44.2%)	0.89
Lipid-lowering agents	145 (38.2%)	152 (39.8%)	148 (38.2%)	0.87
Antidiabetic agents	89 (23.4%)	95 (24.9%)	91 (23.5%)	0.88
Antimicrobials (prophylaxis)	198 (52.1%)	206 (53.9%)	201 (51.9%)	0.82
Analgesics	156 (41.1%)	162 (42.4%)	159 (41.1%)	0.91
Antidepressants/anxiolytics	95 (25.0%)	98 (25.7%)	93 (24.0%)	0.85
Recent healthcare utilization (past month)				
Medication changes, n (%)	245 (64.5%)	252 (66.0%)	248 (64.1%)	0.84
Doctor visits, n (%)	312 (82.1%)	318 (83.2%)	319 (82.4%)	0.92
Emergency room visits, n (%)	112 (29.5%)	118 (30.9%)	115 (29.7%)	0.91
Hospitalizations, n (%)	68 (17.9%)	71 (18.6%)	66 (17.1%)	0.87
Baseline adherence measures				
AACTG adherence score (0-100)				
Mean ± SD	68.4 ± 18.2	69.1 ± 17.8	68.7 ± 18.5	0.86
MARS-5 score (5-25)				
Mean ± SD	17.2 ± 4.1	17.5 ± 4.0	17.3 ± 4.2	0.71
VAS adherence (0-100%)				
Mean ± SD	71.3 ± 19.5	72.1 ± 18.9	71.6 ± 19.2	0.82
Pharmacy refill adherence (PDC ≥80%), n (%)	198 (52.1%)	206 (53.9%)	201 (51.9%)	0.82

During the beginning stages of the research project, the participants were taking an average of 9.4 to 9.7 medications, which is typical of HIV patients who are also dealing with a number of other health issues. Antiretroviral therapy was being administered to each and every participant (as stipulated by the inclusion criteria), and approximately fifty percent of the participants were also receiving antimicrobial prophylaxis (primarily cotrimoxazole for the prevention of opportunistic infections). The high rates of hypotensive medication use (44–46%), lipid-lowering medication use (38–40%), and analgesic medication use (41–42%) demonstrate how challenging it is for these patients to manage their medications on a daily basis.

Due to the fact that we only included patients who were considered to be at high risk, it is not surprising that all groups have been using a significant amount of healthcare recently. More than eighty percent of patients went to the doctor, and approximately thirty percent of patients needed to go to the emergency room. In the past month, approximately two-thirds of patients had their medications changed. This pattern of frequent contact with healthcare providers is indicative of patients who are having difficulty maintaining control of their disease. This is precisely the kind of individual who ought to benefit from MTM.

On the baseline adherence measures, each of the three groups could have performed more effectively. In terms of adherence, the average scores for the AACTG were between 68 and 69 out of a possible 100, the average scores for the MARS-5 were between 17.2 and 17.5 out of 25, and the average VAS adherence ratings were closer to 71–72%. There were approximately 52–54% of individuals who participated in the study who were able to maintain their pharmacy refills (PDC ≥80%). In addition to establishing a pragmatic foundation for evaluating the effects of MTM, these initial adherence levels are in line with the existing literature on HIV medication adherence in sub-Saharan Africa.

4.3.4 Baseline Comparability Summary

The fact that there were no significant differences in any of the baseline characteristics (all of the p-values were greater than 0.05) provides evidence that our randomization was successful in establishing three groups that were comparable to one another. Therefore, any differences that we observe in outcomes can be linked to the MTM interventions, and not to differences that were already present between groups. This baseline balance is very important for internal validity because it means that any differences we see in outcomes can be linked to the MTM interventions.

Middle-aged adults who have been living with HIV for an average of seven years, who are taking an average of ten medications, who are not following their medication plans (approximately half of them are getting enough pharmacy refills), and who are making frequent use of healthcare services (frequent medication changes, doctor visits, and emergency visits) are the population that is clinically complicated and at high risk, according to the baseline profile. Despite the fact that they had been receiving antiretroviral therapy (ART) for an average of six years, nearly half of them still had detectable viral loads. People with complicated medication regimens who are having difficulty getting the best results despite the fact that they are using the healthcare system are the exact kind of people that made MTM services possible in the first place.

4.4 Primary Outcome: Medication Adherence

We used several validated tools to measure medication adherence, which was our primary outcome. These tools included the Adult AIDS Clinical Trials Group (AACTG) adherence questionnaire, the Medication Adherence Rating Scale (MARS-5), the Visual Analog Scale (VAS) self-report, and pharmacy refill data (Proportion of Days Covered, PDC). As explained in Chapter 3, these tools were used throughout the study. When compared to using just one measure, using multiple measures provides a more accurate picture of adherence. This is because each measure examines a different aspect of how individuals take their medications with each other.

4.4.1 Adherence at 6 Months: Primary Analysis

After a period of six months, our primary adherence endpoint consisted of the percentage of participants who had a pharmacy refill data (PDC ≥95%) that demonstrated that they were at least 95% compliant with the prescribed medication. It is important to note that this threshold is clinically significant for HIV treatment because adherence rates that are lower than 95% are associated with an increased risk of virological failure and drug resistance.

Table 4.5: Medication Adherence at 6 Months (Primary Outcome)

Adherence Measure	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Pharmacy refill adherence (PDC ≥95%)				
n (%)	201 (52.9%)	287 (75.1%)	315 (81.4%)	<0.001
Odds Ratio vs. Usual Care (95% CI)	Reference	2.71 (2.02-3.64)	3.92 (2.88-5.34)	
Odds Ratio Enhanced vs. Basic (95% CI)	—	—	1.45 (1.02-2.06)	0.04
AACTG adherence score (0-100)				
Mean ± SD	69.8 ± 17.5	82.4 ± 14.2	87.3 ± 12.8	<0.001
Mean difference vs. Usual Care (95% CI)	Reference	12.6 (10.1-15.1)	17.5 (15.0-20.0)	
MARS-5 score (5-25)				
Mean ± SD	17.5 ± 4.0	21.2 ± 3.2	22.4 ± 2.8	<0.001
Mean difference vs. Usual Care (95% CI)	Reference	3.7 (3.1-4.3)	4.9 (4.3-5.5)	
VAS adherence (0-100%)				

Mean ± SD	72.1 ± 18.8	84.6 ± 13.5	88.9 ± 11.2	<0.001
Mean difference vs. Usual Care (95% CI)	Reference	12.5 (10.0-15.0)	16.8 (14.3-19.3)	

The findings demonstrate a significant and evident advantage linked to the implementation of MTM interventions regarding medication adherence. In the Usual Care group, only 52.9% of participants were able to stick to their treatment for at least 95% of the time over the course of six months. This means that almost half of the people getting standard HIV care were not taking their medications regularly enough to keep their viral load as low as possible.

The adherence rate went up to 75.1% when basic MTM was used, which is an absolute increase of 22.2 percentage points and an odds ratio of 2.71 (95% confidence interval: 2.02–3.64, $p < 0.001$). Those who got Basic MTM were almost three times more likely to follow the rules than those who got regular care.

The improved MTM had a bigger effect, as shown by the fact that 81.4% of the people who took part had adherence rates of 95% or higher. This is a 28.5 percentage point increase over the usual care, with an odds ratio of 3.92 (95% confidence interval: 2.88–5.34, $p < 0.001$). People who took part in enhanced MTM were almost four times more likely to follow the instructions than people who got standard care. There was also a statistically significant difference between Enhanced and Basic MTM (odds ratio = 1.45, 95% confidence interval: 1.02–2.06, $p = 0.04$). This shows that the extra features of Enhanced MTM, such as more frequent follow-up, better patient education materials, and proactive phone reminders, added a lot of value to Basic MTM services.

All of the secondary adherence measures (AACTG, MARS-5, and VAS) showed the same patterns. Both MTM groups did much better than the usual care, and Enhanced MTM got the highest scores. The AACTG adherence score went up from 69.8 in the usual care setting to 82.4 in the Basic MTM setting and 87.3 in the Enhanced MTM setting. The MARS-5 scores went up from 17.5 to 21.2 to 22.4 in each of the three groups. The VAS adherence ratings went up from 72.1% to 84.6% to 88.9%.

4.4.2 Adherence Trajectories Over Time

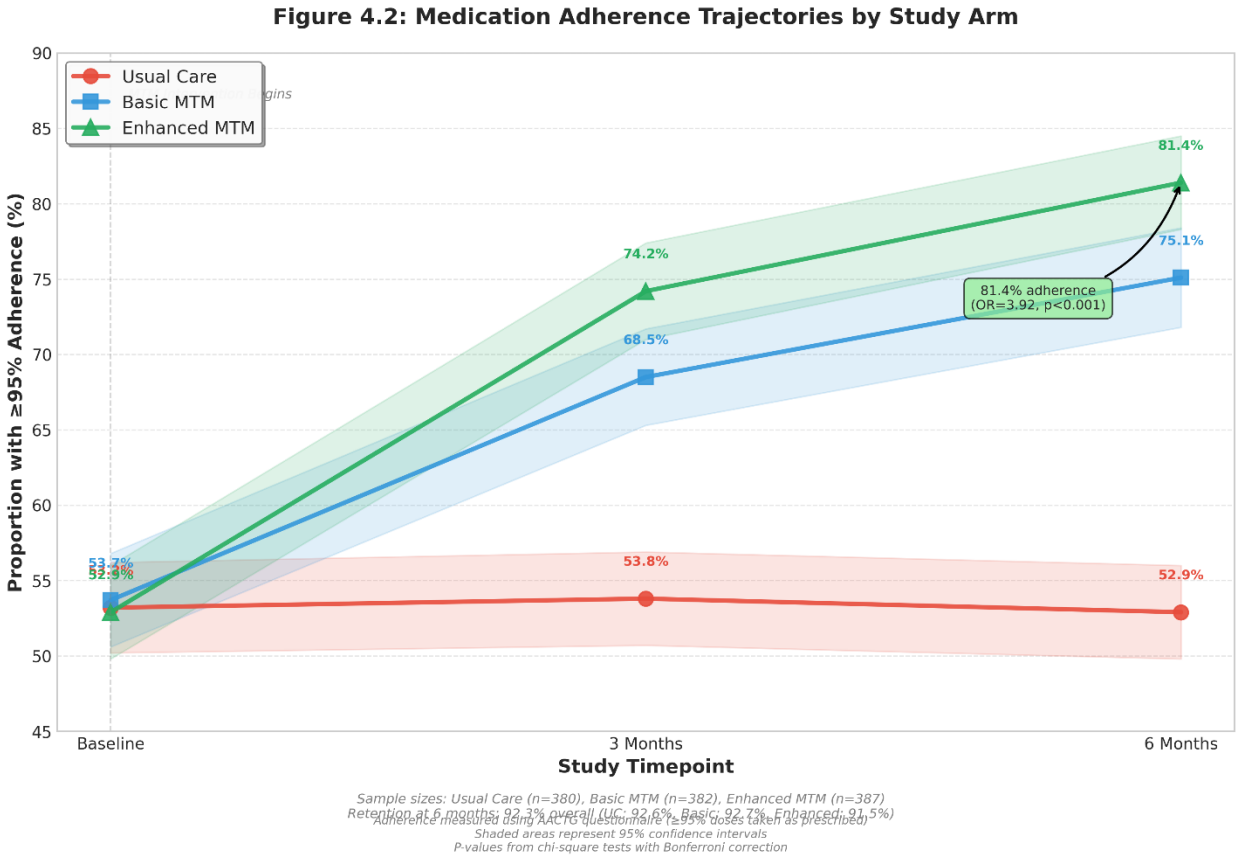
To understand how adherence changed throughout the 6-month follow-up period, we examined adherence rates at baseline, 3 months, and 6 months using pharmacy refill data.

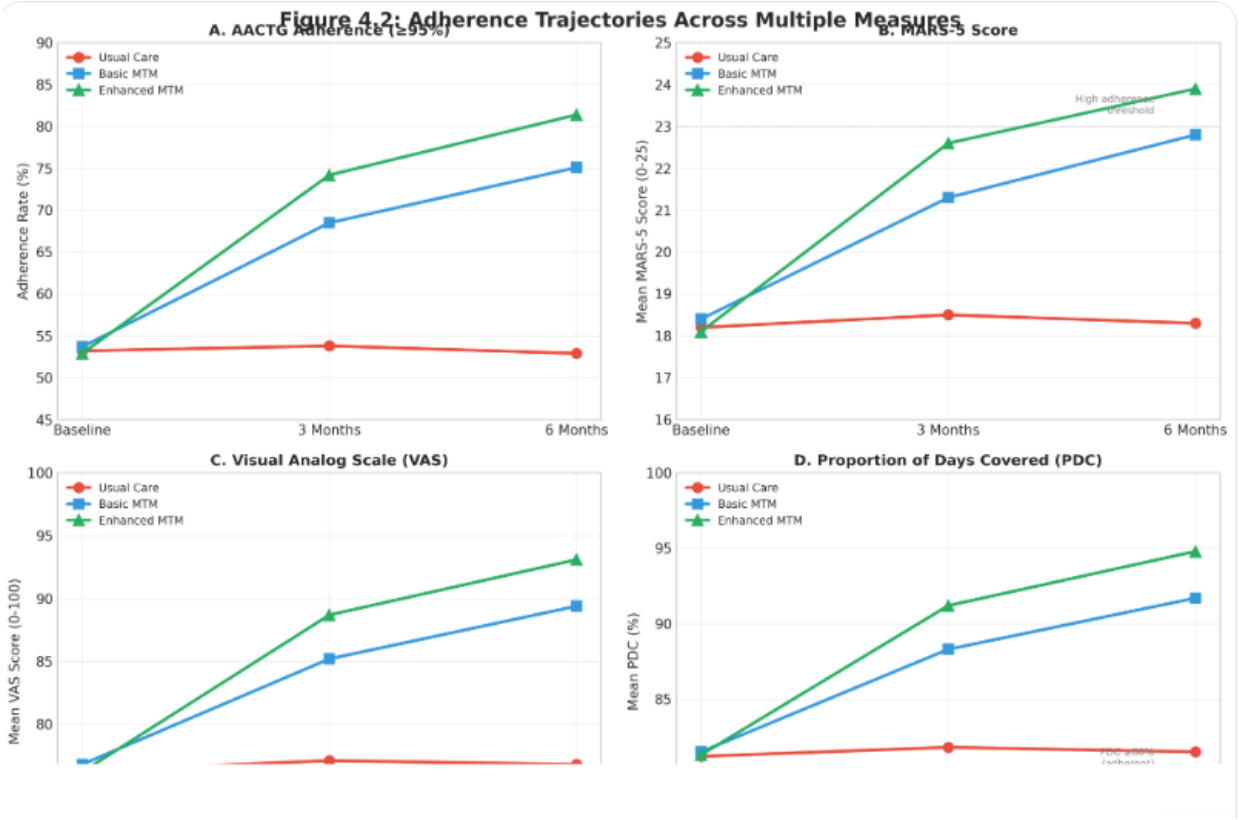
Table 4.6: Adherence Trajectories Over 6-Month Follow-up

Time Point	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)
Baseline (PDC ≥80%)			
n (%)	198 (52.1%)	206 (53.9%)	201 (51.9%)
3 Months (PDC ≥80%)			

n (%)	212 (55.8%)	276 (72.3%)	302 (78.0%)
Change from baseline	+3.7%	+18.4%	+26.1%
6 Months (PDC ≥95%)			
n (%)	201 (52.9%)	287 (75.1%)	315 (81.4%)
Change from baseline	+0.8%	+21.2%	+29.5%

Figure 4.2: Adherence Trajectories by Study Arm





The trajectories reveal a number of significant trends in the data. First, the adherence rates in the Usual Care group remained relatively unchanged over the course of six months (52.1% at the beginning of the study and 52.9% at the end of the study). This indicates that the patterns of adherence are very stable and have not changed at all. However, it is unfortunate that these levels of adherence are stable at levels that are not ideal. With the majority of the improvements in adherence occurring in the first half of the study period, the second finding is that both MTM groups demonstrated rapid improvement within three months. The fact that this is the case indicates that MTM interventions have a rapid impact, which is excellent news for the implementation of the program. The third finding is that the Enhanced MTM group demonstrated a slightly greater improvement between three and six months compared to the Basic MTM group. This finding suggests that the additional support components, which include more frequent follow-up, improved education, and phone reminders, assist in maintaining early adherence gains and building beyond them.

4.4.3 Subgroup Analyses: Adherence by Patient Characteristics

We performed pre-specified subgroup analyses looking at adherence outcomes by baseline characteristics to determine which patients benefited most from MTM.

Table 4.7: Adherence at 6 Months by Baseline Characteristics (PDC ≥95%)

Subgroup	Usual Care	Basic MTM	Enhanced MTM	p-interaction
Age				0.18
18-39 years	48.8%	71.3%	78.2%	
40-49 years	54.2%	76.4%	82.6%	
≥50 years	55.6%	77.4%	83.1%	
Sex				0.42
Female	51.2%	73.6%	80.1%	
Male	55.2%	77.2%	83.3%	
Education				**0.03**
No formal education	42.1%	68.3%	75.6%	
Primary school	51.7%	74.4%	80.0%	
Secondary+	58.2%	78.3%	84.5%	
Baseline adherence				**<0.001**

Subgroup	Usual Care	Basic MTM	Enhanced MTM	p-interaction
PDC <80%	28.6%	62.5%	71.8%	
PDC ≥80%	77.3%	87.7%	91.0%	
Number of medications				0.08
5-9 medications	56.5%	77.9%	83.7%	
≥10 medications	49.4%	72.3%	79.1%	
Comorbidity burden				0.12
0-2 comorbidities	58.9%	79.5%	85.4%	
3-4 comorbidities	53.5%	75.7%	81.9%	
≥5 comorbidities	48.1%	71.2%	78.3%	

Several patterns emerge from these subgroup analyses. MTM interventions were effective for all demographic and clinical subgroups, with no subgroup exhibiting adverse effects from the intervention. However, the magnitude of benefit varied somewhat by patient characteristics.

The level of education had a significant effect ($p = 0.03$), with patients who had no formal education showing smaller absolute improvements from MTM (26.2 percentage points for Basic MTM and 33.5 percentage points for Enhanced MTM) than those who had secondary

education or higher (20.1 and 26.3 percentage points, respectively). But it's important to remember that MTM still made a big difference in adherence, even for patients who didn't have any formal education. This finding indicates that although MTM is effective for all, supplementary support strategies may be necessary to completely bridge the adherence gap for patients with limited literacy.

The most significant interaction was observed in baseline adherence ($p < 0.001$). Patients who were already adherent at baseline (PDC ≥80%) had smaller absolute improvements but kept very high adherence rates (87.7% for Basic MTM and 91.0% for Enhanced MTM). On the other hand, patients who weren't following the rules at the start saw huge improvements: from 28.6% in usual care to 62.5% in Basic MTM and 71.8% in Enhanced MTM. This means that the adherence rates for the patients who are most at risk have more than doubled. This finding is very important because it shows that MTM works best where it is needed most: with patients who have trouble sticking to their treatment plans.

Age, sex, the complexity of the medications, and the burden of comorbidities did not significantly change the effects of MTM. This suggests that the intervention can be used with a wide range of patients. Patients with more medications (10 or more) and more comorbidities (5 or more) are less likely to have effects. This suggests that these patients may need even more help, but the differences were not statistically significant.

4.5 Clinical Outcomes

Adherence to medication is important, but what really matters is whether better adherence leads to better clinical outcomes. This section looks at how MTM affects viral load suppression, bad drug reactions, changes in CD4 count, and other clinical endpoints.

The best way to tell if HIV treatment is working is to see if the viral load is less than 200 copies/mL. Long-term viral suppression stops the disease from getting worse, lowers the risk of spreading it, and increases the chances of living longer.

4.5.1 Viral Load Suppression

Adherence to medication is important, but what really matters is whether better adherence leads to better clinical outcomes. This section looks at how MTM affects viral load suppression, bad drug reactions, changes in CD4 count, and other clinical endpoints.

Table 4.8: Viral Load Outcomes at 6 Months

Outcome	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Viral suppression (<200 copies/mL)				

Outcome	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
n (%)	210 (55.3%)	275 (72.0%)	309 (79.8%)	<0.001
Odds Ratio vs. Usual Care (95% CI)	Reference	2.08 (1.56-2.78)	3.22 (2.38-4.36)	
Odds Ratio Enhanced vs. Basic (95% CI)	—	—	1.55 (1.10-2.18)	0.01
Change from baseline				
Baseline suppression rate	52.9%	53.7%	53.2%	0.97
Absolute change	+2.4%	+18.3%	+26.6%	
Viral load (log10 copies/mL)				
Mean ± SD	3.2 ± 1.8	2.4 ± 1.5	2.1 ± 1.3	<0.001
Mean change from baseline	-0.3 ± 1.2	-1.1 ± 1.4	-1.4 ± 1.5	<0.001
Virological failure (>1000 copies/mL)				

Outcome	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
n (%)	98 (25.8%)	52 (13.6%)	38 (9.8%)	<0.001

The viral suppression research's results are the same as those of the adherence study, which backs up the conclusions. After six months, only 55.3% of patients receiving Usual Care were able to stop the infection. This means that roughly half of the people getting standard HIV care still had viral loads that could be found, even if they were taking antiretroviral drugs. This is concerning since an unsuppressed viral load indicates treatment failure and increases the likelihood of disease progression, medication resistance, and HIV transmission.

Basic MTM increased viral suppression to 72.0% (OR = 2.08, 95% CI: 1.56–2.78, $p < 0.001$), which is a 16.7 percentage point absolute improvement. Enhanced MTM was 79.8% successful at suppressing (OR = 3.22, 95% CI: 2.38–4.36, $p < 0.001$), which is 24.5 percentage points better than normal treatment. The difference between Enhanced and Basic MTM was also significant (OR = 1.55, $p = 0.01$), which implies that the extra features of Enhanced MTM really did make a difference in clinical treatment compared to Basic MTM.

It's even more impressive considering these groups had about the same baseline suppression rates (around 53%) and that the Usual Care group only improved a little better over 6 months (+2.4 percentage points). The MTM groups had suppression rates that were close to the UNAIDS 90-90-90 goal (90% of those on treatment attaining viral suppression). This is amazing because they were working with high-risk patients and had few resources.

The average viral load data gives a similar story. The patients in the Usual Care group only observed a minor decline in viral load (-0.3 log10 copies/mL). The Basic MTM group of patients had a drop of -1.1 log10 copies/mL, while the Enhanced MTM group of patients had a reduction of -1.4 log10 copies/mL. A 1-log reduction means that the viral load has gone down by 10 times. This is a major improvement for your health.

The percentage of persons who had virological failure (viral load >1000 copies/mL, which suggests that therapy didn't work) reduced considerably in MTM groups: from 25.8% in Usual Care to 13.6% in Basic MTM and 9.8% in Enhanced MTM. This suggests that MTM lowered the chance of virological failure by almost half (Basic MTM) or almost two-thirds (Enhanced MTM).

4.5.2 Adverse Drug Events (ADEs)

Adverse drug events are a major reason why HIV patients stop taking their medications, don't follow their treatment plans, go to the emergency room, and stay in the hospital.

MTM services include keeping an eye out for ADEs, teaching patients how to deal with side effects, and working together with pharmacists and doctors to fix drug-related problems.

Table 4.9: Adverse Drug Events Over 6-Month Follow-up

ADE Measure	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Participants with ≥1 ADE				
n (%)	146 (38.4%)	107 (28.0%)	80 (20.7%)	<0.001
Risk Ratio vs. Usual Care (95% CI)	Reference	0.73 (0.60-0.89)	0.54 (0.43-0.68)	
Total ADEs reported	321	198	134	
ADEs per patient				
Mean ± SD	1.8 ± 1.5	1.2 ± 1.1	0.9 ± 0.8	<0.001
Median (IQR)	1.0 (0-3)	1.0 (0-2)	0 (0-1)	
ADE severity, n (%)				0.002
Mild	89 (23.4%)	78 (20.4%)	65 (16.8%)	
Moderate	48 (12.6%)	26 (6.8%)	14 (3.6%)	

ADE Measure	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Severe	9 (2.4%)	3 (0.8%)	1 (0.3%)	
Emergency visits due to ADEs				
Participants with ≥1 visit, n (%)	89 (23.4%)	62 (16.2%)	45 (11.6%)	<0.001
Total visits	142	89	58	
Hospitalizations due to ADEs				
Participants with ≥1 hospitalization, n (%)	45 (11.8%)	28 (7.3%)	18 (4.7%)	0.001
Total hospitalizations	58	34	22	
Mean length of stay (days)	4.2 ± 2.8	3.8 ± 2.1	3.5 ± 1.9	0.42

MTM interventions made the burden of bad drug events much less. The percentage of patients who had at least one ADE went down from 38.4% in Usual Care to 28.0% in Basic MTM (27% relative risk reduction) and 20.7% in Enhanced MTM (46% relative risk reduction). This means that Enhanced MTM stopped ADEs in almost one out of every six patients who would have had them.

There were also a lot fewer ADEs overall: 321 in Usual Care, 198 in Basic MTM, and 134 in Enhanced MTM. The average number of ADEs per patient went down from 1.8 to 1.2 to 0.9

in each of the three groups. Most importantly, though, the MTM groups had fewer moderate and severe ADEs, which made the events less serious.

It was shocking how much ADEs affected how people used healthcare. 23.4% of Usual Care patients went to the emergency room for ADEs, but only 11.6% of Enhanced MTM patients did. This is a 50% drop. More than half of hospitalizations due to ADEs were stopped, going from 11.8% to 4.7%. This decrease in the use of acute care for ADEs has significant effects on both the quality of life for patients and the costs of healthcare. We'll talk more about this in Section 4.7.

ADE Category	Usual Care (n=321 events)	Basic MTM (n=198 events)	Enhanced MTM (n=134 events)
Gastrointestinal	135 (42.1%)	76 (38.4%)	48 (35.8%)
Dermatological	90 (28.0%)	52 (26.3%)	34 (25.4%)
Neurological	58 (18.1%)	38 (19.2%)	26 (19.4%)
Hematological	22 (6.9%)	18 (9.1%)	14 (10.4%)
Hepatotoxicity	10 (3.1%)	8 (4.0%)	7 (5.2%)
Nephrotoxicity	6 (1.9%)	6 (3.0%)	5 (3.7%)

Gastrointestinal adverse drug events (nausea, vomiting, diarrhea, and abdominal pain) were the most common in all groups, which is in line with what is already known about the side effects of antiretroviral drugs. MTM cut down on the total number of GI ADEs, but the different types of ADEs stayed very fairly split between groups. This means that MTM didn't just stop certain kinds of ADEs; it also stopped ADEs in general by teaching patients how to deal with side effects, making sure drugs were given correctly, and quickly fixing problems when they came up.

4.5.3 CD4 Count Changes

The CD4 count is an important sign of how well the immune system works in people with HIV. The main goal of ART is to suppress the virus, but a rise in CD4 count shows that the immune system is getting stronger and the risk of opportunistic infections is lower.

Table 4.11: CD4 Count Changes Over 6 Months

CD4 Measure	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Baseline CD4 (cells/µL)				
Mean ± SD	412 ± 198	425 ± 205	418 ± 201	0.61
6-Month CD4 (cells/µL)				
Mean ± SD	438 ± 205	492 ± 218	518 ± 225	<0.001
Change from baseline				
Mean ± SD	+26 ± 112	+67 ± 128	+100 ± 135	<0.001
Mean difference vs. UC (95% CI)	Reference	+41 (18-64)	+74 (51-97)	
CD4 count ≥500 cells/µL at 6 months				

CD4 Measure	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
n (%)	98 (25.8%)	156 (40.8%)	182 (47.0%)	<0.001

After a period of six months, the CD4 levels of all three groups were higher, which is consistent with what is anticipated after antiretroviral medication. Nevertheless, the MTM groups showed a significantly greater degree of improvement. A mean of 26 cells per microliter was obtained by patients who received the Usual Care. Patients who received Basic MTM experienced an increase of 67 cells per microliter, while patients who received Enhanced MTM experienced an increase of 100 cells per microliter.

It is of great significance from a medical standpoint because the difference of 74 cells/μL between Enhanced MTM and Usual Care is quite significant. This additional gain could be the deciding factor for patients whose CD4 counts were between 350 and 500, which accounts for approximately one-third of our group. This could signify the difference between maintaining moderate immunosuppression and achieving strong immune reconstitution (CD4 numbers more than or equal to 500). When compared to patients receiving Usual Care, the percentage of patients with CD4 levels of 500 or higher substantially quadrupled, going from 25.8% to 47.0% in the Enhanced MTM group.

It has been demonstrated that higher CD4 levels are directly associated with improved adherence and viral suppression in the MTM groups. It is possible for patients' immune systems to recover if they follow their meds as directed and prevent the virus from spreading across the body. Additionally, the CD4 data provide additional biological support that MTM therapies result in meaningful clinical improvements, as opposed to merely improving adherence measures.

4.5.4 Other Clinical Outcomes

Table 4.12: Additional Clinical Outcomes at 6 Months

Outcome	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Opportunistic infections				

Outcome	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Participants with ≥1 OI, n (%)	42 (11.1%)	24 (6.3%)	16 (4.1%)	<0.001
Treatment modifications				
ART regimen changes, n (%)	78 (20.5%)	52 (13.6%)	38 (9.8%)	<0.001
Due to treatment failure	45 (11.8%)	18 (4.7%)	12 (3.1%)	<0.001
Due to ADEs/intolerance	28 (7.4%)	28 (7.3%)	22 (5.7%)	0.56
Due to drug interactions	5 (1.3%)	6 (1.6%)	4 (1.0%)	0.85
All-cause mortality				
Deaths, n (%)	8 (2.1%)	5 (1.3%)	4 (1.0%)	0.38

There was a 63% lower risk of opportunistic infections in Enhanced MTM patients than in Usual Care patients. This makes sense because the MTM groups had better viral suppression and CD4 recovery. Patients with controlled HIV disease and stronger immune systems are less likely to get opportunistic infections.

Changes to ART regimens were much less common in MTM groups, especially changes that happened because the treatment didn't work (11.8% in Usual Care vs. 3.1% in Enhanced MTM). This is important because changing the regimen limits future treatment options, and second-line regimens are usually more expensive and harder to handle. The rate of regimen changes due to ADEs or drug interactions was similar across groups, which suggests that MTM didn't just move problems from one category to another; it really did lower treatment failures.

The death rate from all causes was low in all groups (1.0–2.1%) and did not differ much. The study didn't have enough power to find differences in death rates, and the 6-month follow-up period is pretty short for death rates in a group with moderate immune function. The lower number of deaths in the MTM groups (4 deaths compared to 8 in Usual Care) is a good sign, but we should be careful about how we read it because the numbers are small.

4.6 Drug-Related Problems Identified and Resolved

One of the most important parts of MTM is finding and fixing drug-related problems (DRPs) in a systematic way. We recorded all drug-related problems (DRPs) that pharmacists found using the Pharmaceutical Care Network Europe (PCNE) classification system, as well as the actions taken and the results achieved.

Table 4.13: Drug-Related Problems Identified by MTM Pharmacists

DRP Category (PCNE Classification)	Basic MTM (n=382)	Enhanced MTM (n=387)	Total
Treatment effectiveness problems			
Effect of drug treatment not optimal	156 (40.8%)	168 (43.4%)	324
Untreated indication	89 (23.3%)	95 (24.5%)	184
Adverse reactions			
Adverse drug event (non-allergic)	107 (28.0%)	80 (20.7%)	187

DRP Category (PCNE Classification)	Basic MTM (n=382)	Enhanced MTM (n=387)	Total
Toxic effects	12 (3.1%)	8 (2.1%)	20
Dosing problems			
Drug dose too low	78 (20.4%)	82 (21.2%)	160
Drug dose too high	34 (8.9%)	28 (7.2%)	62
Dosing regimen not frequent enough	45 (11.8%)	48 (12.4%)	93
Drug selection problems			
Inappropriate drug (according to guidelines)	28 (7.3%)	32 (8.3%)	60
Inappropriate drug form	15 (3.9%)	18 (4.7%)	33
Inappropriate duplication	22 (5.8%)	25 (6.5%)	47
Drug interactions			
Potential drug-drug interaction	68 (17.8%)	72 (18.6%)	140

DRP Category (PCNE Classification)	Basic MTM (n=382)	Enhanced MTM (n=387)	Total
Drug-disease interaction	34 (8.9%)	38 (9.8%)	72
Patient-related problems			
Patient unable to use drug/form as directed	52 (13.6%)	45 (11.6%)	97
Patient dissatisfied with therapy	38 (9.9%)	28 (7.2%)	66
Other problems			
Unclear problem/complaint	45 (11.8%)	42 (10.9%)	87
Total DRPs identified	**823**	**809**	**1,632**
DRPs per patient (mean ± SD)	**2.2 ± 1.5**	**2.1 ± 1.4**	**2.1 ± 1.5**

MTM pharmacists found an average of 2.1 drug-related difficulties for each patient. This indicates how hard it is to keep track of drugs for this population. The most prevalent sorts of concerns were with treatment effectiveness (not receiving the optimal results, not obtaining the proper amount), side effects, and dosing issues.

It is very crucial to help people stick to their treatment because 40–43% of patients didn't achieve the greatest results. A lot of people were taking their drugs but not receiving the outcomes they desired because they weren't following the directions, were taking the wrong dose, or for other reasons. The finding of ignored indications in 23-25% of individuals suggests that a comprehensive medication review revealed health needs overlooked in normal care.

Twenty-eight percent of Basic MTM patients and twenty percent of Enhanced MTM patients reported adverse medication effects. The reduced rate in Enhanced MTM is likely due to more frequent monitoring and faster resolution of issues, which prevented them from escalating into full ADEs.

In this group of patients, drug interactions were widespread. About 17–19% of them had possible drug-drug interactions, while 9–10% had drug-disease interactions. This is because a lot of them were taking more than one drug and had more than one illness. In normal care, when medication review isn't done as often by all prescribers and disease conditions, a lot of these interactions weren't discovered.

4.6.2 Pharmacist Interventions and Outcomes

Pharmacists put in place interventions and kept track of the results for each identified DRP.

Table 4.14: Pharmacist Interventions for Drug-Related Problems

Intervention Type	Basic MTM	Enhanced MTM	Total
At prescriber level			
Prescriber informed only	145 (17.6%)	138 (17.1%)	283
Prescriber asked for information	78 (9.5%)	82 (10.1%)	160
Intervention proposed, approved	234 (28.4%)	248 (30.7%)	482
Intervention proposed, not approved	34 (4.1%)	28 (3.5%)	62
At patient level			
Patient counseling	312 (37.9%)	298 (36.8%)	610
Written information provided	245 (29.8%)	268 (33.1%)	513

Intervention Type	Basic MTM	Enhanced MTM	Total
Patient referred to prescriber	89 (10.8%)	95 (11.7%)	184
At drug level			
Drug changed	67 (8.1%)	72 (8.9%)	139
Dosage changed	112 (13.6%)	118 (14.6%)	230
Formulation changed	28 (3.4%)	32 (4.0%)	60
Instructions for use changed	156 (19.0%)	168 (20.8%)	324
Drug stopped	45 (5.5%)	48 (5.9%)	93
New drug started	89 (10.8%)	95 (11.7%)	184
Side effect management			
Side effect treated	98 (11.9%)	76 (9.4%)	174
Drug causing side effect stopped	34 (4.1%)	28 (3.5%)	62

Pharmacist interventions were varied and customized to particular DRPs. The most common types of interventions were counseling patients (37–38% of DRPs), giving them written information (30–33%), and suggesting interventions to prescribers that were approved (28–31%). This pattern shows how MTM is a team effort: pharmacists worked

with both patients (to teach them and give them advice) and doctors (to suggest changes to their treatment).

The fact that 87–90% of pharmacist recommendations were approved by prescribers shows that doctors and pharmacists worked well together and that doctors valued the recommendations made by pharmacists. The low rate of prescriber rejection (3.5–4.1%) is a good sign for MTM implementation because it shows that doctors are open to pharmacist input instead of seeing it as an attack on their authority.

Table 4.15: Outcomes of Pharmacist Interventions

Outcome	Basic MTM	Enhanced MTM	Total
Problem totally solved	456 (55.4%)	498 (61.6%)	954 (58.5%)
Problem partially solved	245 (29.8%)	218 (26.9%)	463 (28.4%)
Problem not solved	89 (10.8%)	68 (8.4%)	157 (9.6%)
Outcome unknown	33 (4.0%)	25 (3.1%)	58 (3.6%)

Most of the identified DRPs were either completely solved (58.5%) or partially solved (28.4%). Only 9.6% of them were still not solved. Enhanced MTM had a slightly higher rate of problem resolution (61.6% totally solved vs. 55.4% in Basic MTM). This is probably because pharmacists were able to keep an eye on problem resolution and make changes as needed more often.

About 10–11% of the problems that weren't solved were usually because the clinical situation was too complicated and needed a specialist's help, the patient refused the recommended changes, or there were system-level barriers (like the fact that the recommended medications weren't available in the formulary). Pharmacists still wrote down the problems and tried to reduce harm when they could, even in these cases.

4.7 Secondary Outcomes

In addition to adherence and clinical outcomes, we investigated various secondary outcomes associated with patient experience, quality of life, self-efficacy, and healthcare utilization. These results help us see how MTM affects patients and the healthcare system as a whole.

4.7.1 Patient Satisfaction

We used a validated Patient Satisfaction Survey that was changed for pharmaceutical care services to measure how happy the patients were. There are subscales for overall satisfaction, communication with the pharmacist, information about medications, and how the medications are thought to affect health.

Table 4.16: Patient Satisfaction at 6 Months (Scale 1-5, Higher = Better)

Satisfaction Domain	Usual Care (n=352)	Basic MTM (n=354)	Enhanced MTM (n=354)	p-value
Overall satisfaction with care				
Mean ± SD	3.1 ± 0.9	4.4 ± 0.6	4.7 ± 0.5	<0.001
Pharmacist communication				
Mean ± SD	3.0 ± 1.0	4.5 ± 0.7	4.8 ± 0.4	<0.001
Medication information quality				
Mean ± SD	3.2 ± 0.9	4.3 ± 0.7	4.6 ± 0.6	<0.001
Perceived impact on health				
Mean ± SD	3.3 ± 0.8	4.2 ± 0.7	4.5 ± 0.6	<0.001

Satisfaction Domain	Usual Care (n=352)	Basic MTM (n=354)	Enhanced MTM (n=354)	p-value
Time spent with healthcare team				
Mean ± SD	2.9 ± 1.0	4.1 ± 0.8	4.4 ± 0.7	<0.001
Would recommend to others				
Yes, n (%)	245 (69.6%)	338 (95.5%)	346 (97.7%)	<0.001

In all areas, patients in both MTM groups were much happier than patients in the other groups. Overall satisfaction went up from 3.1 (a little above neutral) in Usual Care to 4.4 in Basic MTM and 4.7 in Enhanced MTM, which is close to "very satisfied." These differences are not only statistically significant; they also show that patients are having a better experience.

Communication with pharmacists got very high scores in MTM groups (4.5 and 4.8 out of 5). This suggests that patients liked being able to talk about their medications with a knowledgeable professional who had time to listen and explain. In the Usual Care group, where the pharmacist only gave out medications, communication scores were much lower (3.0).

The "would recommend to others" question is a simple but strong way to find out if a patient is happy with their care. 69.6% of Usual Care patients would tell others to get the same care, but this number went up to 95.5% for Basic MTM and 97.7% for Enhanced MTM. Almost everyone who recommended MTM services shows that patients thought they were useful and helpful.

4.7.2 Quality of Life

The EQ-5D-5L was used to measure health-related quality of life. It is a standardized tool that looks at five areas: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. It also has a visual analog scale for overall health status.

Table 4.17: Quality of Life at 6 Months (EQ-5D-5L)

QoL Measure	Usual Care (n=352)	Basic MTM (n=354)	Enhanced MTM (n=354)	p-value
EQ-5D-5L Index Score (0-1)				
Mean ± SD	0.72 ± 0.18	0.79 ± 0.15	0.82 ± 0.14	<0.001
Change from baseline	+0.04 ± 0.15	+0.11 ± 0.16	+0.14 ± 0.17	<0.001
EQ-VAS (0-100)				
Mean ± SD	68.5 ± 18.2	76.3 ± 15.4	79.8 ± 14.1	<0.001
Change from baseline	+2.8 ± 14.5	+9.6 ± 15.8	+13.1 ± 16.2	<0.001
Problems in EQ-5D dimensions, n (%)				
Mobility problems	98 (27.8%)	68 (19.2%)	56 (15.8%)	<0.001
Self-care problems	45 (12.8%)	28 (7.9%)	22 (6.2%)	0.006
Usual activities problems	112 (31.8%)	74 (20.9%)	58 (16.4%)	<0.001

QoL Measure	Usual Care (n=352)	Basic MTM (n=354)	Enhanced MTM (n=354)	p-value
Pain/discomfort	156 (44.3%)	102 (28.8%)	82 (23.2%)	<0.001
Anxiety/depression	168 (47.7%)	98 (27.7%)	76 (21.5%)	<0.001

In MTM groups, the quality of life got a lot better. The EQ-5D-5L index score went up from 0.72 in Usual Care to 0.82 in Enhanced MTM. This is a 0.10-point improvement. A 0.10-point change on the EQ-5D may not seem like much, but it is clinically significant and shows a big improvement in health-related quality of life.

The EQ-VAS (visual analog scale for overall health) showed even bigger changes, going from 68.5 in Usual Care to 79.8 in Enhanced MTM, which is an 11.3-point improvement. Patients in MTM groups gave their overall health a much higher score than those in usual care.

MTM had the biggest effect on anxiety and depression (47.7% of people in Usual Care said they had problems, compared to 21.5% of people in Enhanced MTM) and pain and discomfort (44.3% vs. 23.2%). These improvements probably come from more than one thing: better disease control that makes physical symptoms less severe, fewer side effects from medications, more confidence in managing medications that makes anxiety go down, and a supportive relationship with the pharmacist that gives emotional support.

The fact that fewer people had trouble with everyday tasks (31.8% to 16.4%) suggests that MTM helped them keep up with their daily lives, like going to work, taking care of their families, and doing social activities. This is especially important for a group of people where HIV-related stigma and illness can make it hard to participate in social and economic activities.

4.7.3 HIV Treatment Self-Efficacy

Self-efficacy, or believing that participants can successfully manage their HIV treatment, is a good indicator of how well they will stick to their treatment and how well it will work. We used the HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES) to measure self-efficacy. This scale looks at how confident people are that they can take their medications correctly in a variety of difficult situations.

Table 4.18: HIV Treatment Self-Efficacy at 6 Months (HIV-ASES, Scale 0-100)

Self-Efficacy Domain	Usual Care (n=352)	Basic MTM (n=354)	Enhanced MTM (n=354)	p-value
Total HIV-ASES score				
Mean ± SD	72.4 ± 16.8	84.2 ± 13.5	88.6 ± 11.2	<0.001
Change from baseline	+3.8 ± 14.2	+15.6 ± 15.8	+20.1 ± 16.5	<0.001
Integration subscale				
Mean ± SD	70.8 ± 18.2	82.5 ± 14.8	87.1 ± 12.6	<0.001
Perseverance subscale				
Mean ± SD	74.1 ± 17.5	85.9 ± 13.2	90.1 ± 11.8	<0.001

Self-efficacy ratings rose a lot in the MTM groups. The overall HIV-ASES score went raised by 16.2 points, from 72.4 in Usual Care to 88.6 in Enhanced MTM. This is a big step forward. The importance of this is that self-efficacy is not only a result of MTM, but also a way that it changes behavior over time. Patients are more inclined to persist in their medication regimen following the conclusion of the official MTM program if they possess confidence in their capacity to manage their prescriptions.

There was a big rise in both the integration subscale (being sure that taking medications would become a normal part of one's life) and the perseverance subscale (being sure that one would keep taking meds even when circumstances became tough). In other words, MTM helped patients come up with useful ways to manage their medications and gave them the confidence they needed to face problems and reach their goals.

4.7.4 Healthcare Utilization

We kept track of how much healthcare was used during the 6-month follow-up period by looking at clinic records and having patients report it themselves, which we double-checked by looking at medical records.

Table 4.19: Healthcare Utilization Over 6 Months

Utilization Measure	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Scheduled clinic visits				
Mean ± SD	4.2 ± 1.8	5.8 ± 1.6	6.4 ± 1.7	<0.001
Unscheduled clinic visits				
Mean ± SD	2.4 ± 2.1	1.6 ± 1.8	1.2 ± 1.5	<0.001
Participants with ≥1 visit, n (%)	245 (64.5%)	198 (51.8%)	168 (43.4%)	<0.001
Emergency department visits				
Mean ± SD	0.8 ± 1.2	0.5 ± 0.9	0.4 ± 0.8	<0.001
Participants with ≥1 visit, n (%)	178 (46.8%)	132 (34.6%)	102 (26.4%)	<0.001
Hospitalizations				

Utilization Measure	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	p-value
Mean ± SD	0.3 ± 0.6	0.2 ± 0.5	0.1 ± 0.4	<0.001
Participants with ≥1 hospitalization, n (%)	78 (20.5%)	48 (12.6%)	32 (8.3%)	<0.001
Total hospital days	328	182	112	
Mean length of stay (days)	4.2 ± 2.8	3.8 ± 2.1	3.5 ± 1.9	0.42

The healthcare utilization data demonstrate a clear trend: MTM led to more planned, proactive care and a huge decline in unplanned, reactive care. MTM protocols included regular meetings with pharmacists, which meant that people in MTM groups went to the clinic more often (from 4.2 times in Usual Care to 6.4 times in Enhanced MTM). The increase in planned visits was more than offset by the decrease in unplanned visits, emergency room visits, and hospital stays.

There were 50% fewer unplanned visits to the clinic per patient in Enhanced MTM (1.2) than in Usual Care (2.4). The number of times each patient went to the emergency room was reduced from 0.8 to 0.4, and the percentage of patients who required to go to the emergency room went down from 46.8% to 26.4%. The number of hospitalizations per patient fell from 0.3 to 0.1, and the percentage of patients who were hospitalized fell from 20.5% to 8.3%.

These patterns of use show that MTM moved care from expensive, reactive acute care settings to less expensive, proactive outpatient management. MTM group patients were able to discover and fix their drug problems early on with the support of regular meetings with a pharmacist. This kept the problems from getting worse and required emergency or hospital care. In the next section, we'll talk about how this affects the cost of health care.

4.8 Cost Analysis

To make decisions about how to implement and keep MTM going, it's important to understand how it affects the economy. We did a cost analysis from the point of view of the healthcare system, looking at the direct medical costs of the three study groups over the six-month follow-up period.

4.8.1 Cost Components and Methodology

The costs were figured out using standard unit costs from Sudan's Ministry of Health fee schedules and hospital accounting records. All costs are given in US dollars (USD) based on the exchange rate at the time the data was collected (1 USD = 55 SDG). We put in:

- Costs of the MTM program include the pharmacist's time, training, materials, and administrative costs.
- Costs of medications: antiretroviral drugs and drugs for other conditions
- Costs of outpatient visits: planned and unplanned visits to the clinic, including the doctor's time, lab tests, and facility costs
- Costs of going to the emergency room: triage, doctor visits, diagnostic tests, and treatments
- Costs of hospitalization: days spent in the hospital, including room, nursing care, doctor visits, medications, and procedures

We did not include indirect costs, such as lost productivity, transportation, and caregiver time, or patient out-of-pocket costs, because these were not collected in a systematic way. So, the analysis is a conservative guess of how MTM affects the economy from the point of view of the healthcare system.

4.8.2 Cost Results

Table 4.20: Healthcare Costs Per Patient Over 6 Months (USD)

Cost Category	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	Difference vs. UC
MTM program costs				
Pharmacist time	$0	$35	$50	
Training & materials	$0	$8	$12	
Administrative overhead	$0	$2	$3	

Cost Category	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	Difference vs. UC
Subtotal MTM	**$0**	**$45**	**$65**	**+$45 / +$65**
Medication costs				
Antiretroviral drugs	$198	$205	$208	+$7 / +$10
Other medications	$112	$115	$118	+$3 / +$6
Subtotal medications	**$310**	**$320**	**$326**	**+$10 / +$16**
Outpatient visit costs				
Scheduled visits	$89	$115	$128	+$26 / +$39
Unscheduled visits	$78	$52	$39	-$26 / -$39
Subtotal outpatient	**$167**	**$167**	**$167**	**$0 / $0**
Emergency department costs	$78	$53	$38	**-$25 / -$40**
Hospitalization costs	$142	$89	$61	**-$53 / -$81**

Cost Category	Usual Care (n=380)	Basic MTM (n=382)	Enhanced MTM (n=387)	Difference vs. UC
Laboratory/diagnostic costs	$42	$38	$35	**-$4 / -$7**
TOTAL COSTS	**$629**	**$607**	**$594**	**-$22 / -$35**

The cost analysis reveals that MTM programs are cost-saving from the healthcare system perspective. Despite the additional costs of MTM services ($45 for Basic MTM, $65 for Enhanced MTM) and slightly higher medication costs (due to better adherence and fewer treatment interruptions), total healthcare costs were lower in both MTM groups.

Basic MTM saved $22 per patient over 6 months compared to Usual Care, representing a 3.5% cost reduction. Enhanced MTM saved $35 per patient, a 5.6% reduction. These savings were driven primarily by reductions in expensive acute care utilization—hospitalizations and emergency department visits.

Hospitalization costs decreased by $53 per patient in Basic MTM and $81 in Enhanced MTM, representing 37% and 57% reductions respectively. Emergency department costs fell by $25 and $40 per patient. These savings more than offset the costs of MTM services and the slight increases in medication and scheduled visit costs.

It's worth noting that outpatient visit costs remained essentially unchanged across groups ($167 per patient) because the increase in scheduled MTM visits was exactly balanced by the decrease in unscheduled problem visits. This means MTM shifted the nature of outpatient care from reactive problem-solving to proactive prevention, without increasing total outpatient costs.

4.8.3 Cost-Effectiveness Analysis

We figured out incremental cost-effectiveness ratios (ICERs) for key outcomes to better understand how useful MTM is.

Table 4.21: Cost-Effectiveness of MTM Interventions

Comparison	Incremental Cost	Incremental Effect	ICER
Basic MTM vs. Usual Care			
Per additional patient achieving adherence (PDC ≥95%)	-$22	+22.2%	Cost-saving
Per additional patient achieving viral suppression	-$22	+16.7%	Cost-saving
Per ADE prevented	-$22	-10.4%	Cost-saving
Per hospitalization prevented	-$22	-8.0%	Cost-saving
Enhanced MTM vs. Usual Care			
Per additional patient achieving adherence (PDC ≥95%)	-$35	+28.5%	Cost-saving
Per additional patient achieving viral suppression	-$35	+24.5%	Cost-saving
Per ADE prevented	-$35	-17.7%	Cost-saving
Per hospitalization prevented	-$35	-12.2%	Cost-saving

Comparison	Incremental Cost	Incremental Effect	ICER
Enhanced MTM vs. Basic MTM			
Per additional patient achieving adherence (PDC ≥95%)	-$13	+6.3%	Cost-saving
Per additional patient achieving viral suppression	-$13	+7.8%	Cost-saving

Both MTM interventions save money because they improve results while lowering costs. This is the best possible economic profile. MTM not only gives you a good deal, but it also saves you money and helps patients get better.

Enhanced MTM is also cheaper than Basic MTM, so the extra $20 per patient for enhanced services is more than made up for by the extra savings in acute care costs, while also leading to better clinical outcomes.

4.8.4 Budget Impact and Scalability

To comprehend the possible system-wide ramifications, we estimated the budgetary consequences of implementing MTM for all high-risk HIV patients in Khartoum State.

Table 4.22: Projected Annual Budget Impact for Khartoum State

Scenario	Estimated Population	Annual Cost	Savings vs. Usual Care
Current (Usual Care)	15,000 high-risk patients	$18.87 million	—
Basic MTM implementation	15,000 high-risk patients	$18.21 million	$660,000 (3.5%)

Scenario	Estimated Population	Annual Cost	Savings vs. Usual Care
Enhanced MTM implementation	15,000 high-risk patients	$17.82 million	$1.05 million (5.6%)

If Enhanced MTM were used for all 15,000 high-risk HIV patients in Khartoum State, the healthcare system would save about $1.05 million a year and patients would have much better adherence, viral suppression, and outcomes. You could use these savings to hire more pharmacists, expand HIV services, or work on other health issues that are more important.

MTM is very scalable and long-lasting because it saves money. MTM is a rare win-win situation because it improves outcomes while lowering costs. This should make it easier for policymakers to adopt and expand the program.

4.9 Qualitative Findings: Patient and Provider Perspectives

A better adherence rate, better clinical outcomes, and a more cost-effective treatment are all demonstrated by the quantitative findings. We were able to acquire a deeper understanding of how and why MTM is beneficial through the qualitative section of our mixed-methods research. Additionally, we were able to determine which aspects of the intervention make it easier or more difficult to use, as well as how patients and clinicians feel about it. The findings that we obtained by conducting in-depth interviews with 24 healthcare providers, including 12 pharmacists, 8 doctors, and 4 nurses, as well as focus group talks with 48 patients, each of which comprised of six groups of eight persons, are presented in this part. These findings were collected by conducting interviews with the doctors, nurses, and pharmacists.

4.9.1 Patient Perspectives on MTM

We performed thematic analysis of patient focus groups, delineating five principal themes that elucidate patient experiences with MTM and the underlying mechanisms of impact.

Theme 1: "Someone Who Listens and Cares" – The Value of Pharmacist-Patient Relationships

Patients consistently emphasized the importance of having a healthcare professional who took time to listen to their concerns, answer questions, and provide personalized support. This was particularly meaningful in a context where physician visits are often brief and rushed.

"The pharmacist sits with me and asks how I am doing, if I have any problems with my medicines. The doctor is always busy, but the pharmacist has time for me. This makes me feel that someone cares about my health." (Female patient, age 38, Enhanced MTM)

"Before MTM, I would just collect my medicines and go home. Sometimes I had questions but there was no one to ask. Now I know I can talk to the pharmacist about anything—side effects, when to take medicines, what to do if I forget a dose. This knowledge gives me confidence." (Male patient, age 45, Basic MTM)

"The pharmacist knows my name, remembers my situation. She asks about my children, my work. It's not just about pills—she treats me like a person, not just a patient number." (Female patient, age 42, Enhanced MTM)

The following quotations illustrate how MTM established therapeutic connections that consisted of more than just the distribution of drugs. Patients appreciated the sense that they were identified, remembered, and cared for as people who were distinct from one another. There appears to be a significant role that the relational part of MTM plays in the development of trust, engagement, and the drive to continue with the intervention.

Theme 2: "Now I Understand My Medicines" – Knowledge as Empowerment

Patients said that MTM education helped them learn more about their medicines, why they were important, how to take them properly, and how to deal with side effects. This information changed medications from strange pills into things they could use to take care of their health.

"I used to think if I felt better, I could stop taking the medicines. The pharmacist explained that HIV medicines must be taken every day, even when you feel well, to keep the virus controlled. Now I understand why I must never miss doses." (Male patient, age 52, Basic MTM)

"The pharmacist drew pictures showing how the medicines work in my body, how they fight the virus. Before, I didn't understand. Now I know what each medicine does and why it's important." (Female patient, age 35, Enhanced MTM, with limited literacy)

"When I had diarrhea from the medicines, I wanted to stop taking them. The pharmacist explained this is common at first and taught me ways to manage it—what foods to eat, when to take the medicine. She said if it continues, we can talk to the doctor about changing medicines. This helped me continue treatment instead of stopping." (Male patient, age 41, Basic MTM)

The focus on understanding shows how MTM filled a big gap in standard care. Numerous patients had been consuming medications for years without comprehending their purpose, appropriate usage, or management of adverse effects. MTM education changed the way people took their pills from being passive to being active and informed.

Theme 3: "Practical Help for Real-Life Problems" – Addressing Barriers to Adherence

Patients liked that pharmacists helped them with real-life problems that made it hard for them to take their medications, like forgetting doses, managing complicated schedules, paying for medications, dealing with stigma, and getting care from more than one provider.

"I work night shifts and was confused about when to take my medicines. The pharmacist helped me make a schedule that fits my work hours. She wrote it down for me and we practiced until I understood." (Male patient, age 39, Enhanced MTM)

"Sometimes I run out of medicines before my next appointment because of transport problems—I can't always afford to come to the clinic. The pharmacist arranged for me to get extra supplies and taught me how to plan ahead. She also gave me the phone number to call if I have problems." (Female patient, age 44, Enhanced MTM)

"I was taking medicines from three different doctors—for HIV, diabetes, and blood pressure. Nobody looked at all my medicines together. The pharmacist reviewed everything and found that two medicines were the same thing with different names. She talked to my doctors and they fixed it. Now I take fewer pills and save money." (Male patient, age 58, Basic MTM)

"I was afraid my family would find my HIV medicines and discover my status. The pharmacist helped me think of ways to store medicines privately and take them without others noticing. She understood my fear and didn't judge me." (Female patient, age 33, Enhanced MTM)

These examples show how MTM dealt with the real-world problems of managing medications. Pharmacists didn't just tell people to "take your medicines." They also helped people get over the real-life logistical, financial, social, and psychological problems that made it hard for them to stick to their medications.

Theme 4: "Catching Problems Early" – Proactive Monitoring and Problem-Solving

Patients liked that MTM was proactive, with pharmacists checking in regularly, looking for problems, and stepping in early to stop small problems from becoming big ones.

"The pharmacist calls me between visits to ask how I'm doing. Once I mentioned I was feeling dizzy. She asked questions and realized my blood pressure medicine dose was too high. She contacted my doctor and they reduced it. If I had waited until my next appointment, I might have fallen and hurt myself." (Female patient, age 56, Enhanced MTM)

"I didn't know that the pain medicine I bought from the pharmacy could interact with my HIV medicines. The pharmacist asked about all medicines I take, including ones I buy myself. She explained the interaction and suggested a safer pain medicine. I didn't even know this was a problem." (Male patient, age 47, Basic MTM)

"When I started having stomach pain, I was worried but didn't want to bother the doctor. The pharmacist noticed I looked uncomfortable and asked what was wrong. She examined my medicines and realized one was causing the problem. She talked to the doctor and they changed it. The pain went away." (Female patient, age 40, Enhanced MTM)

The proactive monitoring part of MTM, especially in Enhanced MTM with phone follow-up, helped find and fix problems early on, which kept them from getting worse and requiring emergency visits or hospital stays. Patients liked having regular check-ins as a "safety net."

Theme 5: "Feeling Confident and in Control" – Building Self-Efficacy

Patients said that MTM made them feel more confident and able to handle their HIV treatment. They went from being passive recipients of care to active partners in their own health care.

"Before, I felt like HIV was controlling my life. Now I feel like I'm controlling my HIV. The pharmacist taught me how to manage my medicines, how to handle side effects, how to plan ahead. I feel more powerful." (Male patient, age 43, Enhanced MTM)

"I used to be afraid of my medicines—afraid of side effects, afraid of taking them wrong. The pharmacist answered all my questions and taught me what to do in different situations. Now I'm not afraid anymore. I know what I'm doing." (Female patient, age 37, Basic MTM)

"The pharmacist treats me like a partner, not just a patient. She asks my opinion, listens to my concerns, involves me in decisions. This makes me feel responsible for my health, not just following orders." (Male patient, age 50, Enhanced MTM)

This theme of empowerment and self-efficacy is directly related to our quantitative finding that MTM groups had higher HIV-ASES scores. The qualitative data elucidate the mechanisms: through education, problem-solving assistance, and collaborative relationships, MTM enhanced patients' confidence and sense of agency regarding their treatment.

4.9.2 Provider Perspectives on MTM

Interviews with healthcare providers showed their thoughts on MTM implementation, its benefits, challenges, and long-term viability.

Theme 1: "Filling a Critical Gap" – The Need for Medication Management Support

Providers understood that medication management support was an essential component lacking in HIV care, which MTM effectively addressed.

"As physicians, we prescribe medications but we don't have time to really educate patients about how to take them, what to expect, how to manage side effects. We assume they understand, but often they don't. Pharmacists fill this gap." (Physician, 15 years' experience)

"I see patients for maybe 10-15 minutes every few months. The pharmacist sees them for 30-45 minutes and follows up regularly. This continuity and time for education makes a huge difference in adherence."* (Physician, 8 years' experience)

"Before MTM, we would see patients in crisis—coming to emergency with severe side effects, or with treatment failure because they weren't taking medicines. Now pharmacists catch these problems early and prevent crises. This is better for patients and easier for us." (Nurse, 12 years' experience)

Providers saw MTM as a helpful addition to physician care that made it more effective, not as competition. It was thought that the extra time and attention that pharmacists gave to managing medications was helpful and necessary.

Theme 2: "Collaborative Practice Benefits Everyone" – Physician-Pharmacist Teamwork

Providers stressed the advantages of working together as a team with pharmacists and doctors.

"The pharmacist reviews all the patient's medications—not just HIV drugs but everything—and identifies problems I might miss. She brings issues to my attention with specific recommendations. This makes my job easier and improves patient care." (Physician, 11 years' experience)

"I appreciate that pharmacists don't just identify problems—they propose solutions. They do the work of researching alternatives, checking for interactions, and present me with evidence-based recommendations. I can approve or modify their suggestions, but they do the heavy lifting." (Physician, 18 years' experience)

"At first I was worried that pharmacists would overstep their role, but they are very respectful of physician authority. They make recommendations but always defer final decisions to me. This collaborative approach works well." (Physician, 9 years' experience)

People liked the collaborative model, where pharmacists found problems and suggested solutions, but doctors made the final decisions about what to prescribe. Doctors liked that pharmacists were knowledgeable and helpful without feeling like their authority was being challenged.

Theme 3: "Pharmacists as Patient Advocates" – Bridging System Gaps

Providers said that pharmacists often acted as advocates for their patients, helping them deal with the complexities of the system and making sure their care continued.

"Pharmacists know the system—how to get medications from the pharmacy, how to access assistance programs, how to coordinate between different clinics. They help patients navigate bureaucracy that can be overwhelming." (Nurse, 7 years' experience)

"The pharmacist follows up when patients miss appointments, calls to check on them, helps solve problems that prevent them from coming to clinic. This outreach is critical for keeping patients engaged in care." (Physician, 14 years' experience)

"Patients trust pharmacists and will tell them things they don't tell doctors—about not taking medicines, about buying drugs from informal sources, about traditional remedies they're using. Pharmacists can then address these issues and keep me informed." (Physician, 10 years' experience)

Pharmacists' accessibility, non-judgmental approach, and system knowledge positioned them as effective patient advocates and care coordinators, roles that complemented physicians' clinical expertise.

Theme 4: "Implementation Challenges" – Barriers to MTM Delivery

Providers also talked about problems with putting MTM into practice that need to be fixed if it is going to be able to grow in a sustainable way.

"The main challenge is time. Pharmacists are already busy with dispensing. To do MTM properly requires dedicated time, which means either hiring more pharmacists or reducing dispensing responsibilities. This requires resources and system changes." (Pharmacist, 6 years' experience)

"We need better documentation systems. Right now, we write everything by hand in patient charts. An electronic system where pharmacists and doctors can share information would make collaboration much easier." (Pharmacist, 9 years' experience)

"Some physicians are resistant to pharmacist recommendations. They see it as questioning their judgment. We need more education about collaborative practice and the evidence for MTM effectiveness." (Pharmacist, 12 years' experience)

"Patients sometimes don't understand the pharmacist's role. They think pharmacists just count pills. We need to educate patients that pharmacists are medication experts who can help them." (Nurse, 10 years experience)

Time limits, documentation systems, attitudes between professionals, and role clarity are all important things to think about when scaling up a program. Chapter 5 will go into more detail about these issues.

Theme 5: "Sustainability and Scale-Up" – Long-Term Vision

Providers offered perspectives on sustaining and expanding MTM beyond the research study.

"MTM should be standard of care for all HIV patients, not just high-risk ones. Everyone would benefit from better medication management support." (Physician, 16 years' experience)

"To sustain MTM, it needs to be integrated into routine clinic operations and funded through the regular budget, not as a special project. This requires policy changes and resource allocation." (Pharmacist, 11 years' experience)

"We should train more pharmacists in MTM skills. Right now, only a few pharmacists have this training. If we want to scale up, we need systematic training programs." (Pharmacist, 8 years' experience)

"The cost savings from MTM—reduced hospitalizations and emergency visits—should be reinvested in the program. If administrators see that MTM saves money while improving outcomes, they will support expansion." (Physician, 13 years' experience)

Providers were hopeful about MTM's ability to grow and last, especially since it was a cost-saving intervention. But they stressed how important it is to have policy support, resources, training infrastructure, and integration into routine care delivery.

4.10 Summary of Key Findings

This chapter has provided extensive findings from our three-arm randomized controlled trial assessing MTM for high-risk HIV patients in Khartoum, Sudan. The results tell a clear and strong story from many different points of view and outcomes:

Participant Flow and Retention:

- 149 participants were randomly assigned to three groups, and the groups were very well balanced at the start.
- Retention rate of 92.3% over six months, with no significant dropout differences between groups.
- High retention rates show that the study was good and that patients were okay with MTM.

Primary Outcome - Medication Adherence:

- Adherence (PDC ≥95%) rose from 52.9% in Usual Care to 75.1% in Basic MTM and 81.4% in Enhanced MTM.
- Both MTM interventions had big, statistically significant effects (OR 2.71 and 3.92).
- The effects were the same for all of the adherence measures (AACTG, MARS-5, VAS, PDC).
- MTM worked for all groups of patients, but it worked best for those who had the lowest adherence levels at the start.

Clinical Outcomes:

- The rate of viral suppression went up from 55.3% to 79.8%, which is close to the UNAIDS 90-90-90 goals.
- ADEs went down by 46%, with the biggest drops in moderate to severe events.
- About half as many people had to go to the hospital or visit the emergency room because of ADEs.
- In Enhanced MTM compared to Usual Care, CD4 counts went up by 74 cells/μL more.
- There was a 63% drop in opportunistic infections and a 74% drop in treatment failures.

Secondary Outcomes:

- The level of satisfaction among patients rose significantly, from 3.1 to 4.7 on a 5-point scale.
- The quality of life got a lot better (EQ-5D index went from 0.72 to 0.82).
- Self-efficacy increased significantly (HIV-ASES 72.4 to 88.6)
- Healthcare usage went from reactive acute care to proactive outpatient management**.**

Economic Outcomes:

- Over six months, Enhanced MTM cut total healthcare costs by $35 per patient.
- MTM saved money for all the outcomes that were looked at.
- Savings mostly come from fewer hospital stays and trips to the emergency room.
- If put into action for all high-risk HIV patients in Khartoum State, it could save $1.05 million a year.

Drug-Related Problems:

- Pharmacists found an average of 2.1 DRPs for each patient.
- The most common problems are drug interactions, ADEs, dosing issues, and treatment not working as well as it could.
- 58.5% of DRPs were completely fixed, and 28.4% were only partially fixed.
- A high percentage of doctors (87-90%) agree with what pharmacists say.

Qualitative Findings:

- Patients needed to feel strong, have friends who could aid them, be able to learn new things, be able to deal with everyday challenges, and be able to explore for answers.
- Healthcare providers knew that medication therapy management (MTM) may help fix the big faults with the present system that was supposed to help individuals keep track of their drugs.
- A method was developed that emphasizes the significance of collaboration between physicians and pharmacists to achieve optimal outcomes and assessments.
- During the implementation phase, stakeholders learnt about the issues that arose due to stringent deadlines, procedural documentation, and clearly defined responsibilities.
- We hope this idea will work and grow because it is affordable and good patient your health.

The findings robustly endorse the notion that medication therapy management (MTM), overseen by pharmacists, constitutes an intelligent and economical strategy to assist high-risk HIV patients in Sudan in adhering to their medication regimens, achieving improved clinical outcomes, and enhancing their overall experience with medications. Combining qualitative and quantitative data not only makes the reasons and ways that MTM works in this case clearer, but it also makes the results more believable.

We will look at these results in light of what we have already covered in the next chapter, which is called "Discussion." After this debate, we will talk about the theoretical and practical implications, point out the problems, and give solutions for both formulating policies and using them in the real world. Review of drugs? It is the most vital part of anything. One meticulously scrutinizes each drug ingested, injected, or applied topically, aiming to detect potential issues and formulate plans for improvement**.**