Evaluation of the Facilitators and Barriers

to Achieving Targets on the HIV Continuum of Care

A DISSERTATION

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DEDICATION

For Mom, Dad, Catherine, and Molly.

ABSTRACT

Key targets on the HIV Continuum of Care include diagnosis, receiving HIV-specific care, and viral suppression. However, many persons living with HIV are not reaching these important thresholds. The goal of this dissertation was to examine facilitators and barriers to achieving these steps on the HIV Continuum of Care.

First, I examined the role of user engagement with three major components of *Thrive with Me (TWM)*, an mHealth intervention, on viral suppression. Among users, engagement with the *TWM* intervention was high. High overall engagement with *TWM* was found to be associated with viral suppression at the end of the active intervention period. Of the individual *TWM* components, only engagement with asynchronous peer exchanges was associated with achieving viral suppression.

Second, I evaluated the relationship between individual-level and social-level factors on patient activation, a measure of an individual's ability to be engaged with their health care, among a sample of men who have sex with men living with HIV. Overall patient activation was high in this sample. Social support and antiretroviral therapy (ART) related information, motivation, and behavioral skills may increase patient activation while increased life chaos, perceived stress, HIV-related stigma, and stimulant drug use may decrease patient activation.

Finally, I examined the association of individual, social, and structural level facilitators and barriers to engagement in care among Ethiopians initiating HIV care. Decreased HIV knowledge, the inability to carry out normal activities, social isolation, and transportation were barriers to being retained in HIV care within one-year of

initiating HIV treatment. In the long-term, HIV disclosure and social support may facilitate sustained engagement in HIV care.

The results of the manuscripts presented in this dissertation help to identify potential areas of intervention to improve steps on the HIV Continuum of Care, including retention in care and viral suppression.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF COMMON ABBREVIATIONS

ART: Antiretroviral Therapy

CASI: Computer Assisted Survey Instrument

CHW: Community Health Worker

EHE: Ending the HIV Epidemic in the U.S.

HIV: Human Immunodeficiency Virus

GLM: Generalized Linear Models

IMB: Information, Motivation, and Behavioral-Skills

MSM: Men who have Sex with Men

PLWH: Persons Living with HIV

SMS: Short Message/Messaging Service

SNNPR: Southern Nations, Nationalities, and Peoples Region

TWM: Thrive with Me

UNAIDS: Joint United Nations Programme on HIV/AIDS

WHO: World Health Organization

A. INTRODUCTION AND BACKGROUND

A.1. Epidemiology of HIV in the United States

A.1.1 HIV among men who have sex with men in the United States.

It is estimated that 1.2 million people in the United States were living with HIV in 2021, of which men who have sex with men (MSM) are disproportionately affected.[1] Despite that between 1.5% and 6% of the United States population are MSM,[2-4] male-to-male sexual contact accounted for 70% of the more than 32,000 new HIV infections in 2021 and nearly 64% of all persons living with HIV (PLWH).[1] Although incidence of HIV infection has decreased overall since the 1980s, progress in reducing new HIV infection has slowed.[5]

Among MSM, disparities by age and racial and ethnic groups are also apparent. Since 2017, new diagnoses among individuals aged 13 to 24 years old have decreased while all other age groups have remained stable since 2017.[1] However, MSM aged 13 to 24 and 25 to 34 accounted for 23% and 43% of all new diagnoses among MSM in 2021.[1] Similarly, Black / African American MSM and Hispanic / Latino accounted for 38% and 34% of all new diagnoses among MSM in 2021, despite accounting for only 12% and 18% of the overall United States population.[1] Despite a decrease in new infections among white MSM between 2017 and 2021, new diagnoses have remained stable among Black / African American MSM and Hispanic / Latino MSM.[1] MSM aged 13 to 34 accounted for more than 75% of new infection among Black / African American MSM and 65% among Hispanic / Latino MSM.[1] Overall, young (13 to 34) Black / African American and Hispanic / Latino MSM accounted for more than half of all new infections

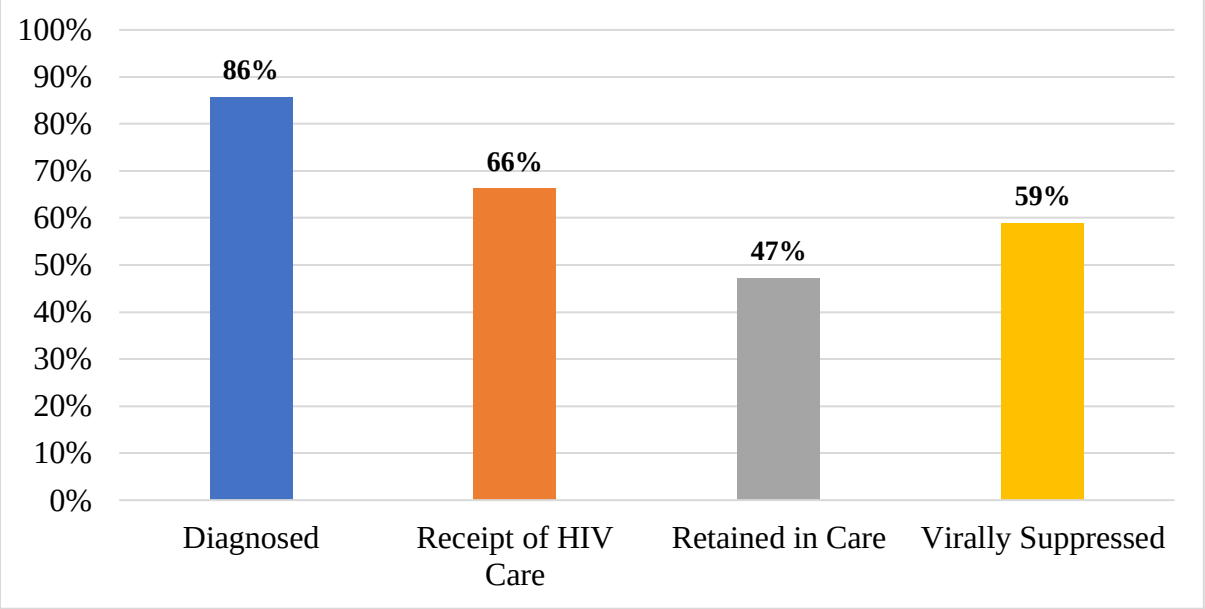
in 2021.[1] Therefore, targeted approaches for addressing the HIV epidemic among MSM and subgroups are important.

A.1.2 HIV Continuum of Care Model

Antiretroviral therapy (ART) has been shown to increase health outcomes among PLWH including improving quality of life,[6-9] and life expectancy.[10-14] Consistent use of ART as prescribed and achieving viral suppression has also been shown to prevent onward transmission to HIV-negative partners.[15-27] It is important to note that this dissertation was completed prior to the approval of a long-acting ART regimen, which is dosed at every 2 months instead of daily doses.[28] The HIV Continuum of Care is a five-step model that tracks important milestones for PLWH as they moves through the steps required to achieve viral suppression.[29,30] Steps include 1) diagnosis of HIV infection; 2) linkage to HIV medical care; 3) receipt of HIV medical care; 4) retention in medical care; and 5) achievement and maintenance of viral suppression(

Figure 1. HIV Continuum of Care Among MSM

a. Prevalence-based HIV Continuum of Care



b. Diagnosis-based HIV Continuum of Care

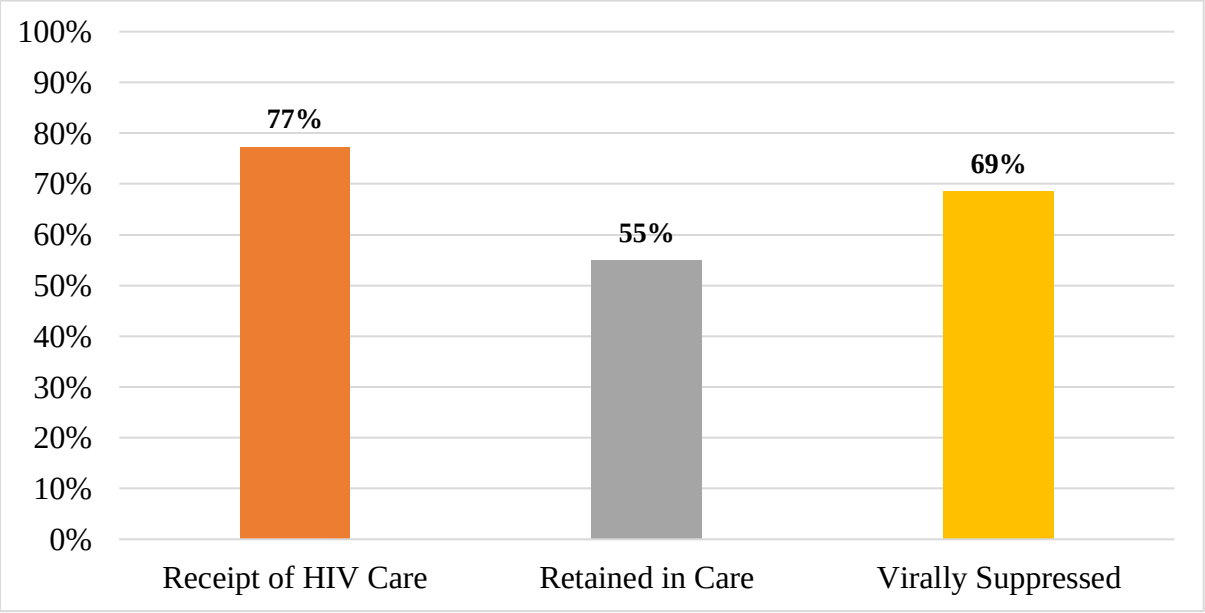
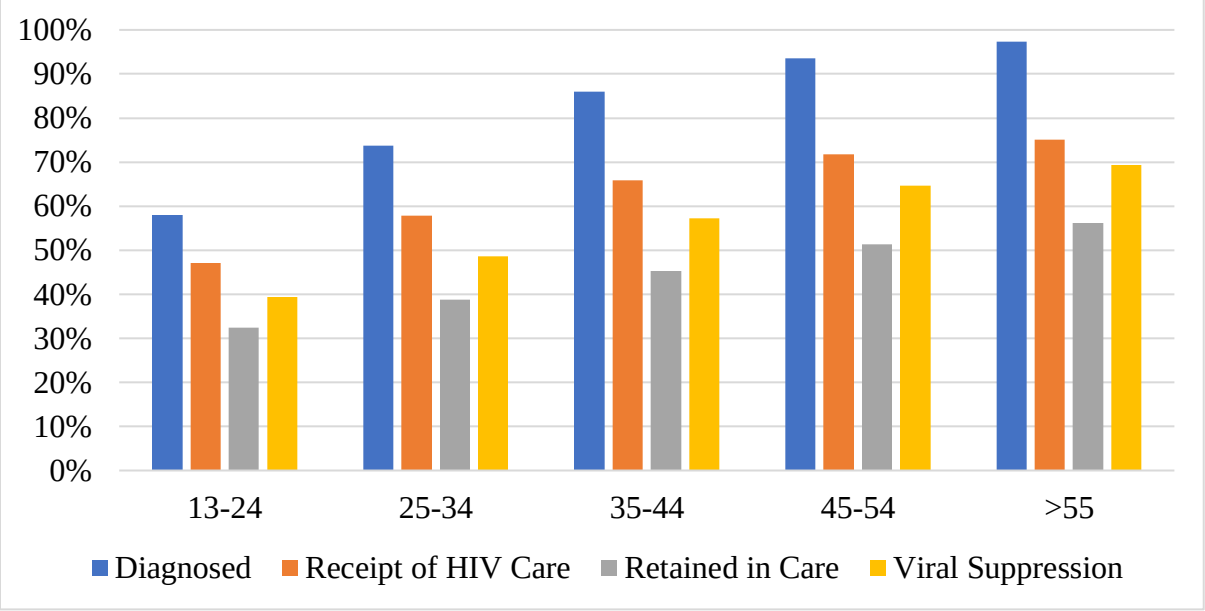


Figure 2. HIV Continuum of Care among MSM (Age)

a. Prevalence-based HIV Continuum of Care



b. Diagnosis-based HIV Continuum of Care

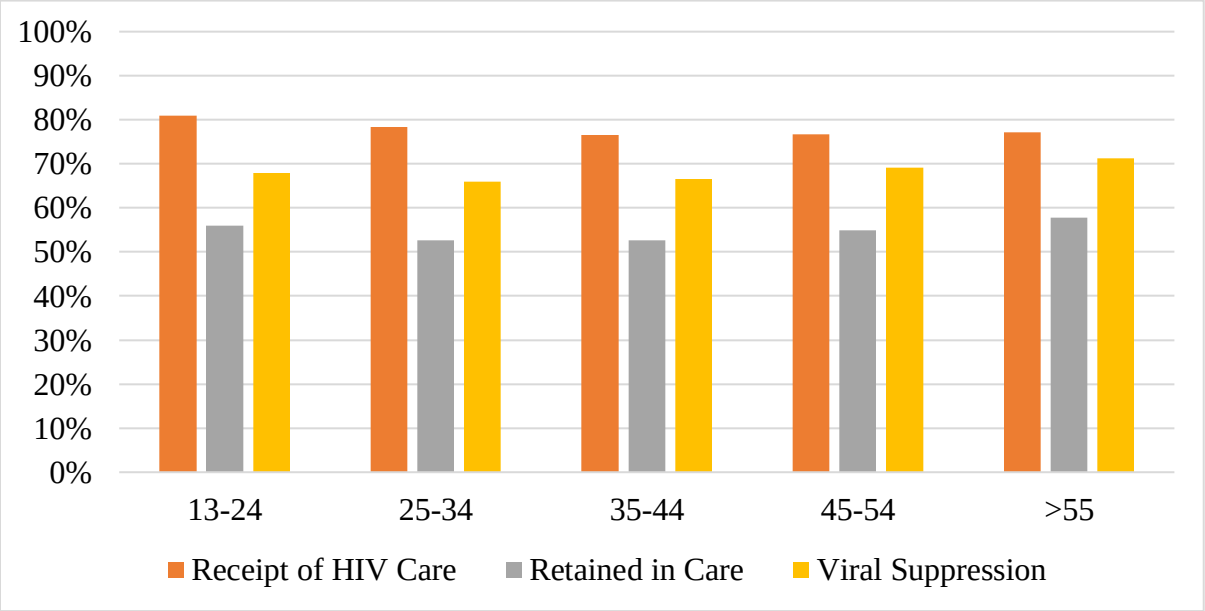
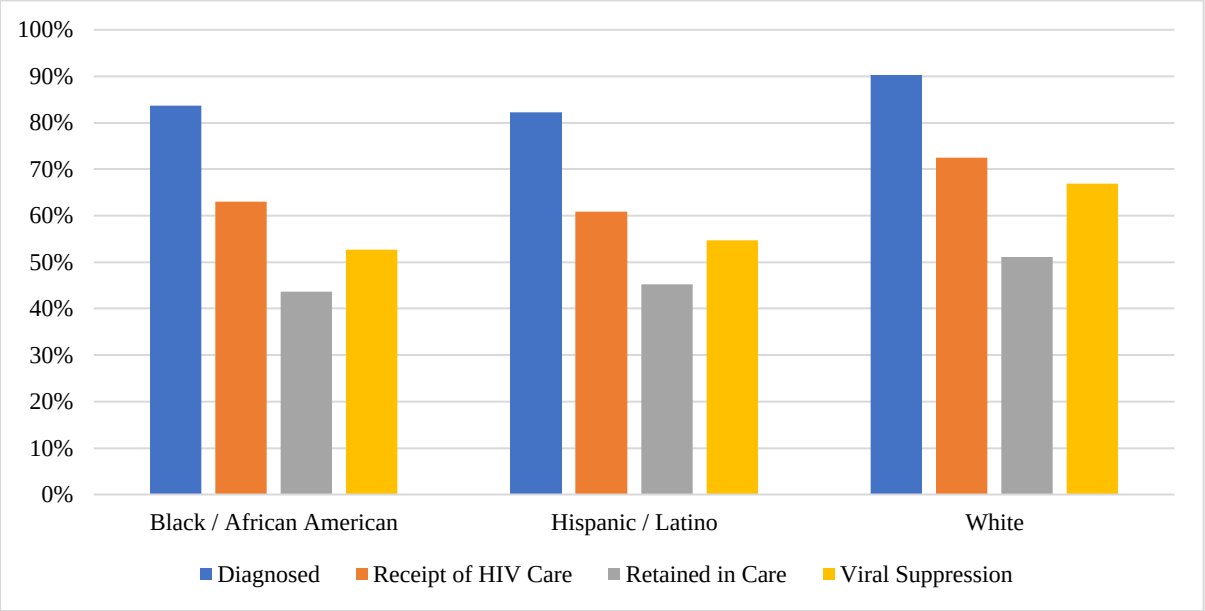


Figure 3. HIV Continuum of Care among MSM (Race / Ethnicity)

a. Prevalence-based HIV Continuum of Care



b. Diagnosis-based HIV Continuum of Care

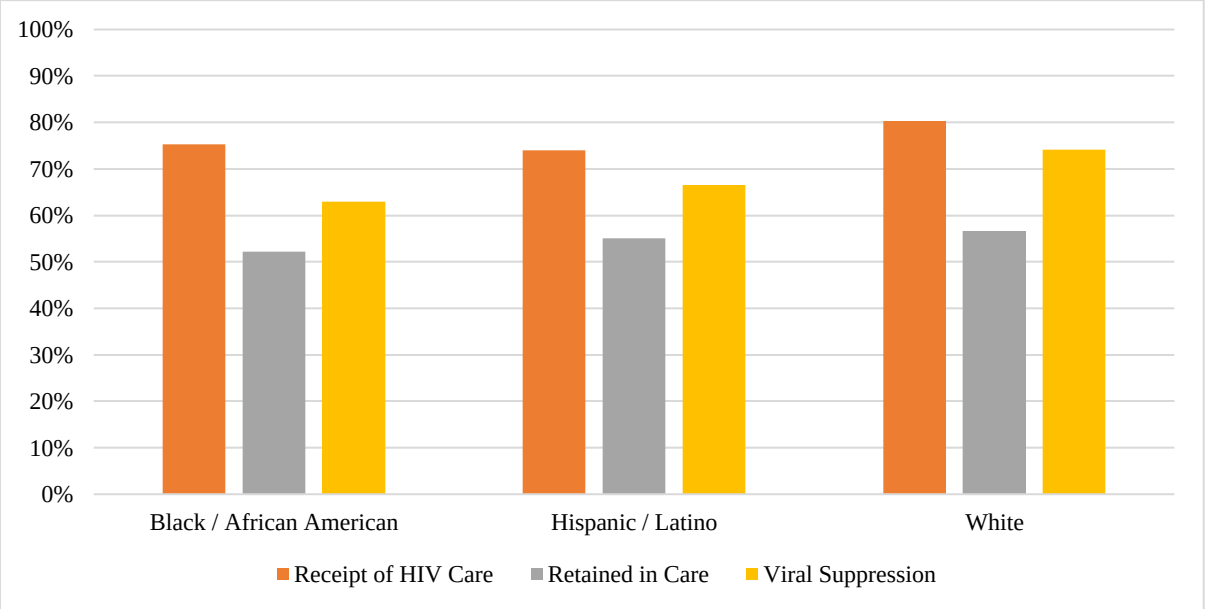


Figure 4. Prevalence-Based HIV Continuum of Care (Ethiopia)

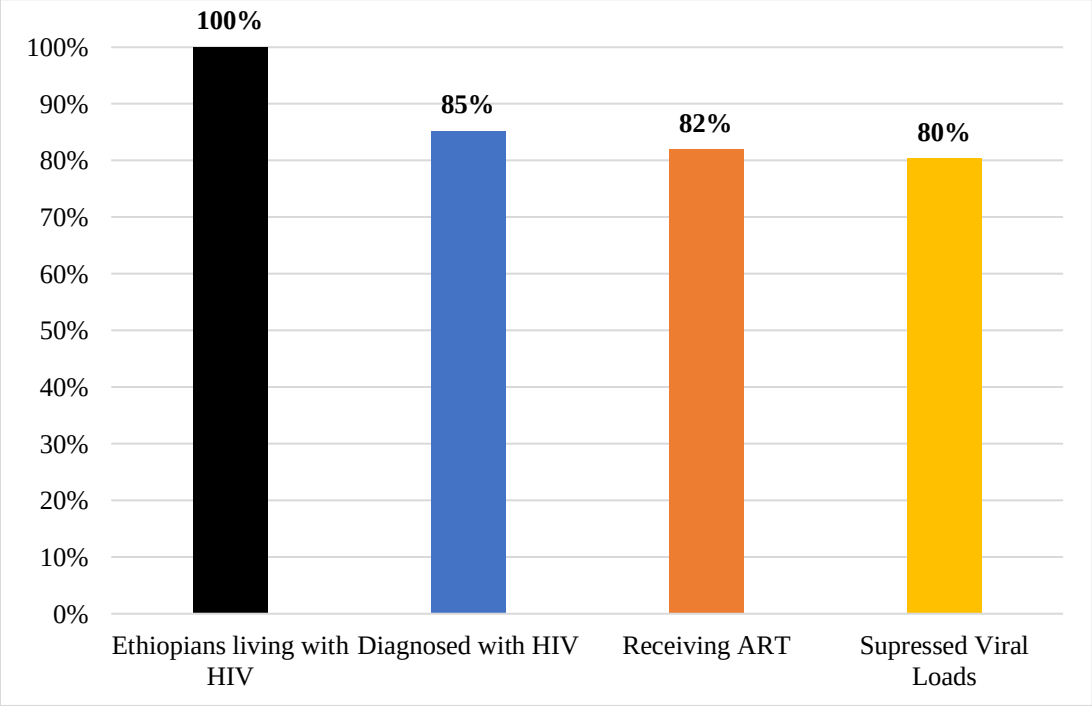


Table 1**).**[29,30]

Current global and national goals utilize the HIV Continuum of Care as benchmarks for progress in ending the HIV epidemic. National goals utilizing this model include the *Ending the HIV Epidemic in the U.S* (EHE). Targeted strategies for this national plan include components of the HIV Continuum of Care, including (1) diagnosis, and (2) treatment with ART to achieve viral suppression. These goals include a 90% reduction in new HIV infections and 95% of individuals diagnosed with HIV achieving viral suppression in the United States by 2030.[31,32]

A.1.3 Current Estimates of the HIV Continuum of Care among MSM

Current national estimates suggest that in 2021 in the United States, 87% of all PLWH and 86% of MSM were diagnosed and knew their status.[1,33] These estimates vary by racial and age subgroups. While more than 90% of white MSM know their status, only 82% of Hispanic / Latino MSM know their status and 84% of Black / African American MSM.[1,33] Similar disparities are found among age groups, while more than 96% of those aged 55 and older know their HIV status, only 56% of those aged 13 to 24 and 73% of those aged 25 to 34 know their status.[1,33] Progress among young MSM has been made as only 41.5% of MSM aged 13 to 24 knew their status in 2017.[1,33]

Nationally, 75% of those diagnosed with HIV received some HIV care, 54% were considered retained in care, while 66% were considered virally suppressed.[33] Similar estimates were found among MSM: 77% received some HIV medical care, 55% were retained in care and 69% were virally suppressed (Figure 1).[33] Disparities among MSM

along the HIV Continuum of Care by age and race and ethnicity are found in Figure 2 and Figure 3.

An additional step on the HIV Continuum of Care is linkage to care

(Figure 4. Prevalence-Based HIV Continuum of Care (Ethiopia)

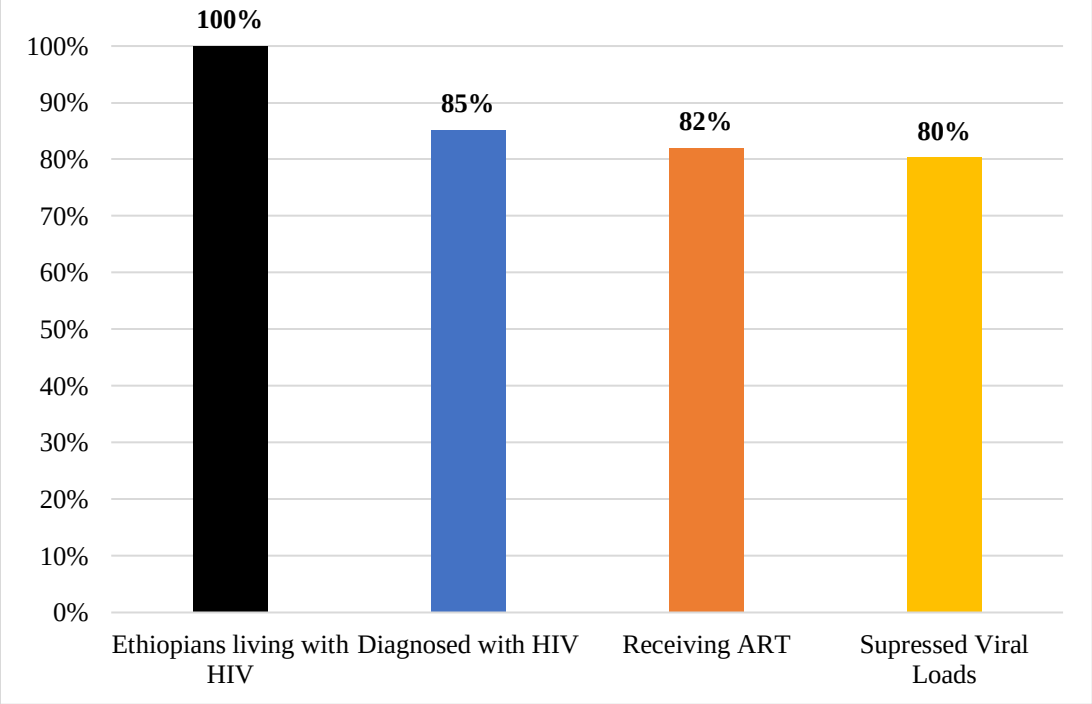


Table 1).[29,30]

Overall, metrics on the HIV Continuum of Care among MSM have increased since 2014. Linkage to HIV care within one month of diagnosis has increased from 66.2% in 2014 to 82.6% in 2021.[33-35] Viral suppression within six months following diagnosis has also increased; only 51.% were virally suppressed in 2014 compared to 71.2% in 2021.[33-35] Although the metrics on the HIV Continuum of Care are increasing, age and racial disparities are still persistent in both linkage to HIV care as well as viral suppression. Between 2014, African American / Black MSM had largest increase in linkage to medical care after diagnosis, with current estimates of 79.2% linkage to care, but remain lower compared to Hispanic / Latino MSM (84.9%) and White MSM (84.2%).[33,35] Similar trends were found between 2014 and 2021 for percent virally suppressed. Only 66.7% of African American / Black MSM were virally suppressed within 6 months of diagnosis in 2018 compared to 74.5% of Hispanic / Latino MSM and 72.8% of White MSM.[35]

Improving each step of the HIV Continuum of Care, in particular viral suppression, is not only important for the health of individuals living with HIV, it may also decrease transmission to HIV negative partners.[15-21] It is estimated that individuals living with HIV but who are not diagnosed or diagnosed and not retained in care are responsible for between 80% and 90% of all HIV transmissions.[21,36] In particular, individuals who are receiving HIV care, but are not virally suppressed account for nearly 20% of all HIV transmissions.[21] Therefore, improving viral suppression among individuals living with HIV is crucial. Despite numerous advancements since the beginning of the HIV epidemic, including the use of antiretroviral therapy (ART) for HIV

treatment and prevention, greater efforts are needed to address the challenges MSM still face through the HIV Continuum of Care, in particular linkage and retention in care as well as viral suppression, in particular, among younger individuals, and Black / African American and Hispanic / Latino MSM.[15,22]

A.2. Global Burden of HIV

A.2.1 Global Epidemiology of HIV

It is estimated that approximately 39 million people globally were living with HIV in 2022 and 1.3 million people became newly infected.[37] Globally, women and children, as well as sex workers, MSM, people who inject drugs and transgender people are heavily burdened by the epidemic.[37] Approximately nearly of all PLWH are women or children and nearly 5% are children.[37] Women and girls accounted for nearly two-thirds of new infections in 2022 in sub-Saharan Africa.[37]

Regionally, the majority of the HIV epidemic is centered in eastern and southern Africa, which accounts for approximately 53% of all PLWH in 2020 and approximately 38% of all new HIV infections, followed by Asia and the Pacific (16% of PLWH; 23% of new infections) and western and central Africa (12% of PLWH; 12% of new infections).[37] North America and Western / Central Europe account for approximately 6% of all PLWH and 4% of all new infections.[37] However, since 2010, Eastern and

southern Africa and Western and central Africa have had the largest percent reduction in new HIV infections (57% and 49%, respectively).[38]

Globally, major advancements have been made to fight the HIV epidemic. Since 2000, the number of new HIV infections each year has reduced from 2.9 million individuals to 1.2 million people in 2022.[37] Similarly, the number of individuals who have been able to access ART has risen drastically. In 2015, less than half of PLWH were accessing ART (48%) compared to 76% in 2022.[37,38] Similar regional disparities are also seen in access to ART. Approximately 76% are able to access ART in North America and Western and central Europe, while 83% of PLWH living in Eastern / Southern Africa, and 82% living in Western and Central Africa are accessing ART.[37] Less than 60% of PLWH are accessing ART in the Middle East and North Africa (51%) and Eastern Europe and central Asia (51%).[37]

A.2.2 Current Global HIV Continuum of Care

In 2014, UNAIDS proposed the 90-90-90 strategy aimed at have 90% of all PLWH diagnosed, 90% of those diagnosed receiving ART, and 90% of those receiving ART virally suppressed by 2025 and end the AIDS Epidemic by 2030 (95% of all PLWH diagnosed, 95% of those diagnosed receiving ART, and 95% of those receiving ART virally suppressed).[39,40] Current global HIV Continuum of Care metrics have improved since 2015. The percent of people living with HIV who know their status has increased from 71% in 2015 to 86% in 2022.[37,38] The percent of people living with HIV who are on treatment has increased 58% from 48% in 2015 to 76% in 2022, while those who are

virally suppressed has increased more than 78% from 40% to 71%.[37,38] Since 2014, there are currently five countries that have met the 95-95-95 targets, while 16 countries have reached the 90-90-90 targets.[38] Despite progress, additional work is needed to meet both UNAIDS targets worldwide.

A.2.3 Current HIV Continuum of Care in Ethiopia

Ethiopia is one of the countries that has seen the largest reduction in new HIV infections between 2010 and 2022, with nearly a 70% decrease.[38] In 2022, it is estimated that approximately 8,300 individuals were newly diagnosed with HIV and approximately 610,000 Ethiopians were living with HIV.[38,41] Of those PLWH in Ethiopia, approximately 85% know their status, 82% are on ART, and 80% have suppressed viral loads (Figure 4).[41,42] These are comparable to the current HIV Continuum of Care for Eastern and Southern Africa; among PLWH, 92% know their status, 83% are on ART treatment, and 77% are virally suppressed.[38]

A.3. Statement of Purpose

This dissertation aims to identify facilitators and barriers to achieving steps on the HIV Continuum of Care in the United States and Ethiopia. The objectives of this dissertation are as follows.

Manuscript 1 Objective: Evaluate the role of user engagement with an mHealth intervention on viral suppression among MSM living with HIV.

1. Describe demographic, behavioral, and psychosocial differences between users and non-users of the *Thrive with Me* intervention.
2. Determine the association of overall user engagement with the *TWM* intervention on viral suppression among *TWM* participants.
3. Assess the associations of user engagement of the *TWM* components (1) asynchronous peer exchanges, (2) HIV and ART-related information content, and (3) ART self-monitoring features on viral suppression among *TWM* participants.

Manuscript 2 Objective: Evaluate the association between individual-level and social-level factors on patient activation in a sample of MSM living with HIV.

1. Evaluate the association between individual-level factors (Information-Motivation-Behavioral Skills for ART Adherence, drug use, alcohol use, depression, life chaos, and perceived stress) and patient activation.
2. Evaluate the association between social-level factors (HIV-related stigma and social support) and patient activation.

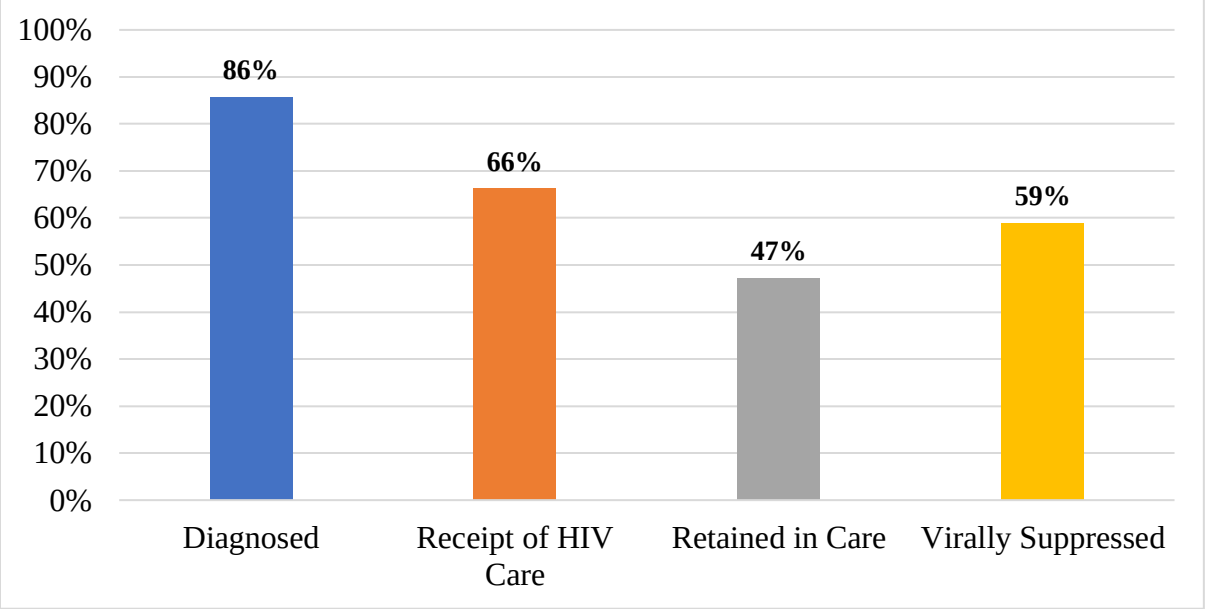
Manuscript 3 Objective: Evaluate the association of individual-level, social-level, and structural-level barriers and facilitators to retention in care among a sample of Ethiopians initiating HIV care in the SNNPR region of Ethiopia.

1. Evaluate the association of individual-level (HIV knowledge, physical symptoms, and depression) facilitators and barriers to retention in care at month-12 and month-36 among Ethiopians initiating HIV care.

2. Evaluate the association of social-level (internalized stigma, social isolation, HIV disclosure, and emotional and tangible social support) facilitators and barriers to retention in care at month-12 and month-36 among Ethiopians initiating HIV care.
3. Evaluate the association of structural-level (transportation and time) facilitators and barriers to retention in care month-12 and month-36 among Ethiopians initiating HIV care.

Figure 1. HIV Continuum of Care Among MSM

c. Prevalence-based HIV Continuum of Care



d. Diagnosis-based HIV Continuum of Care

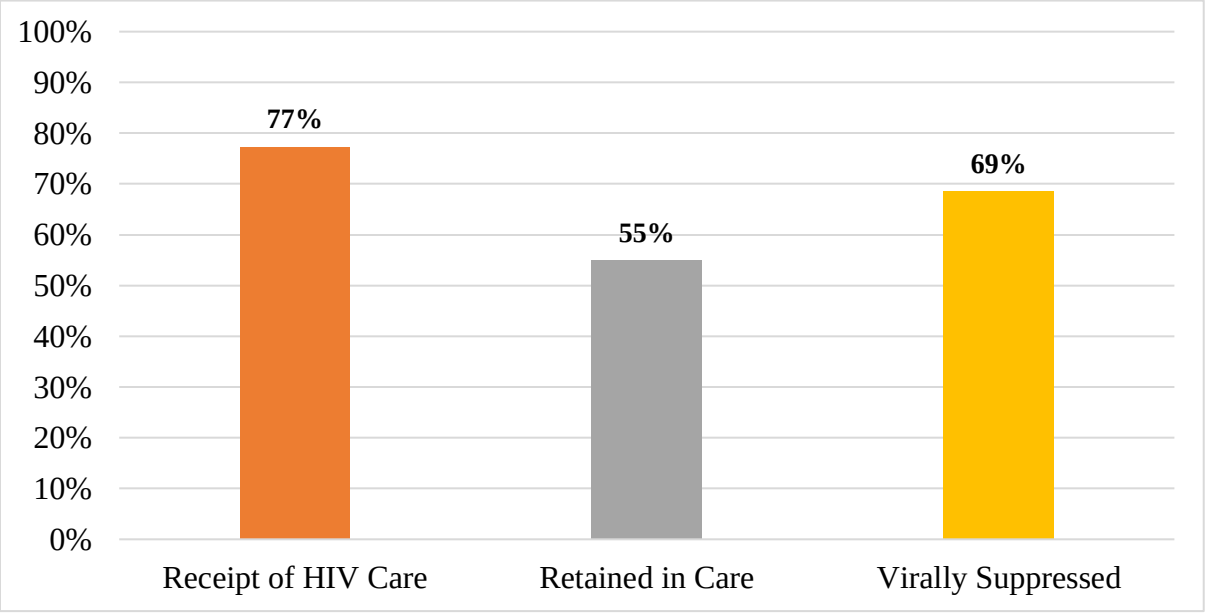
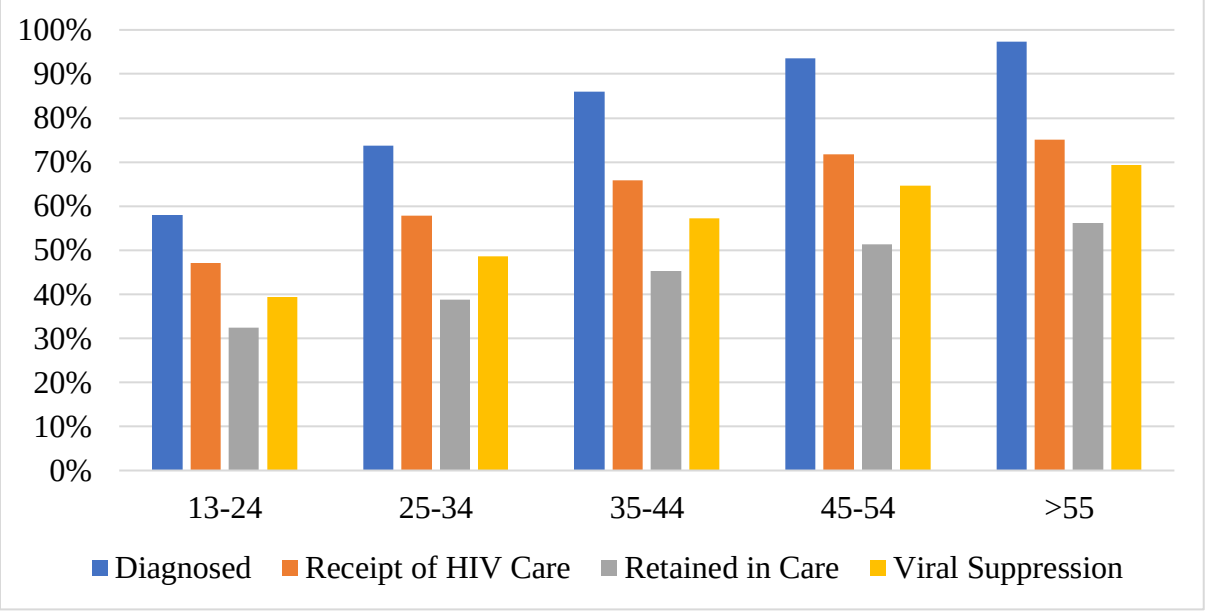


Figure 2. HIV Continuum of Care among MSM (Age)

c. Prevalence-based HIV Continuum of Care



d. Diagnosis-based HIV Continuum of Care

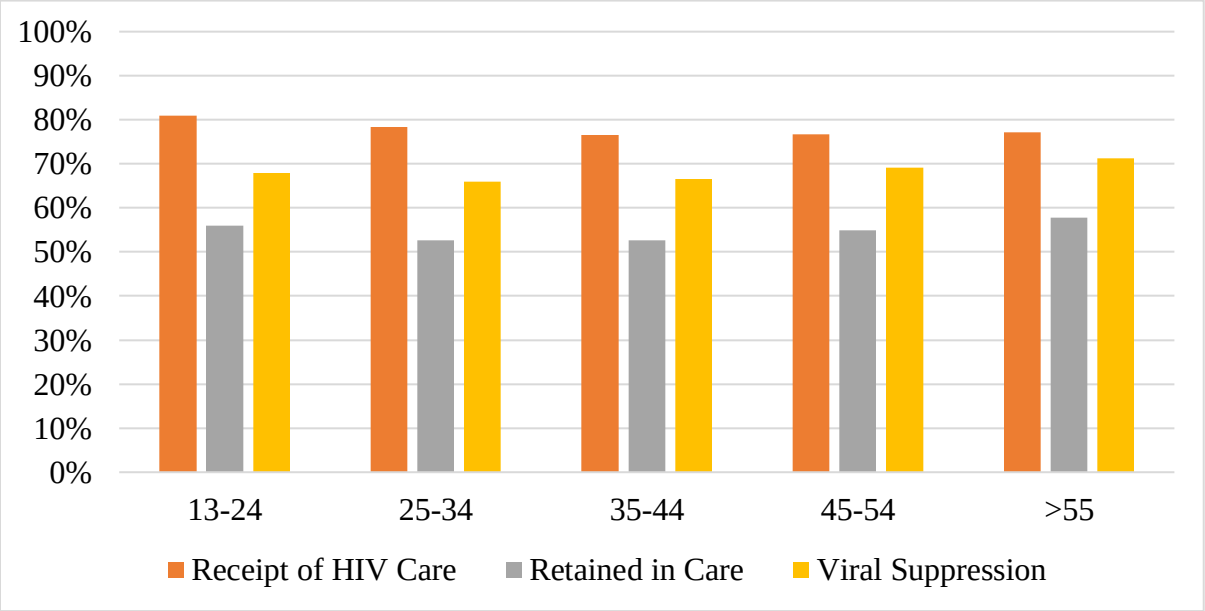
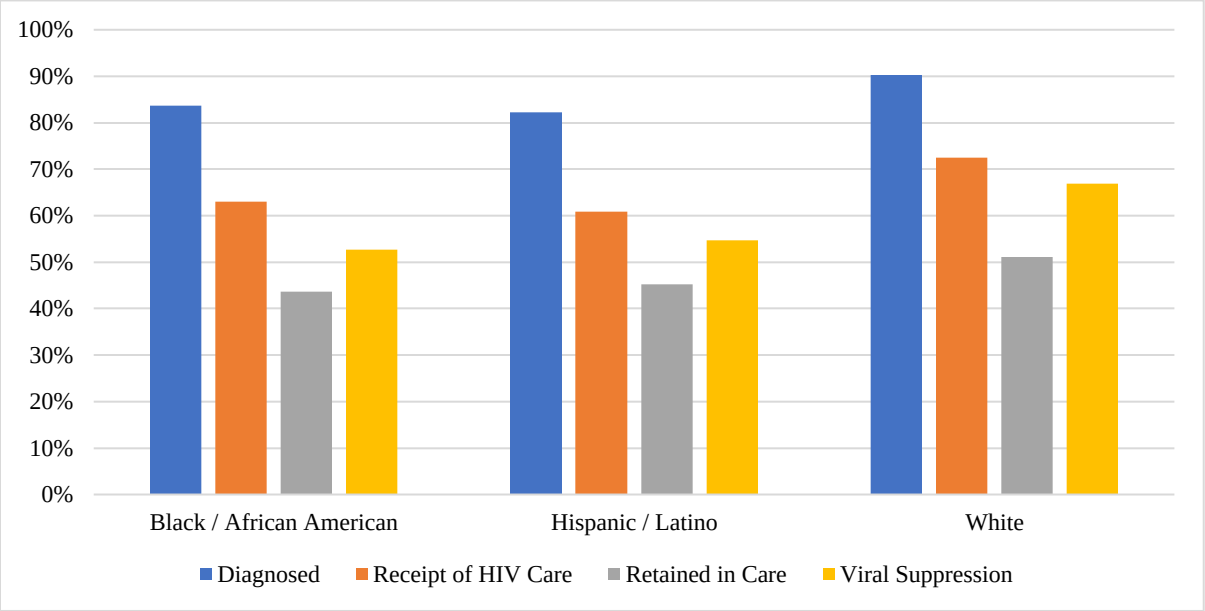


Figure 3. HIV Continuum of Care among MSM (Race / Ethnicity)

c. Prevalence-based HIV Continuum of Care



d. Diagnosis-based HIV Continuum of Care

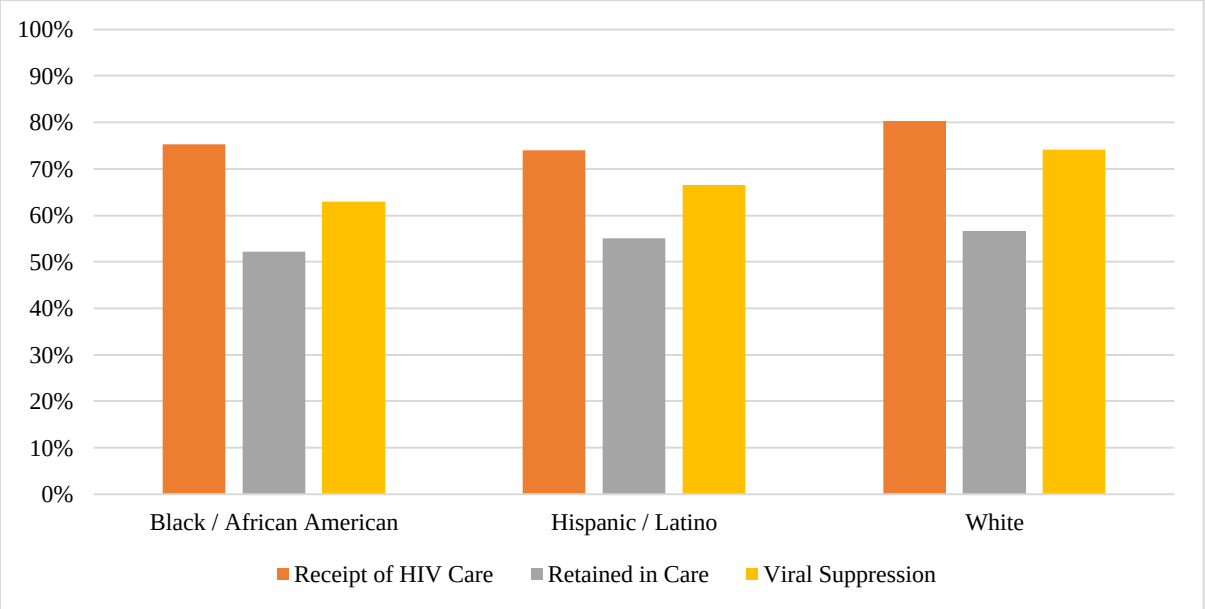


Figure 4. Prevalence-Based HIV Continuum of Care (Ethiopia)

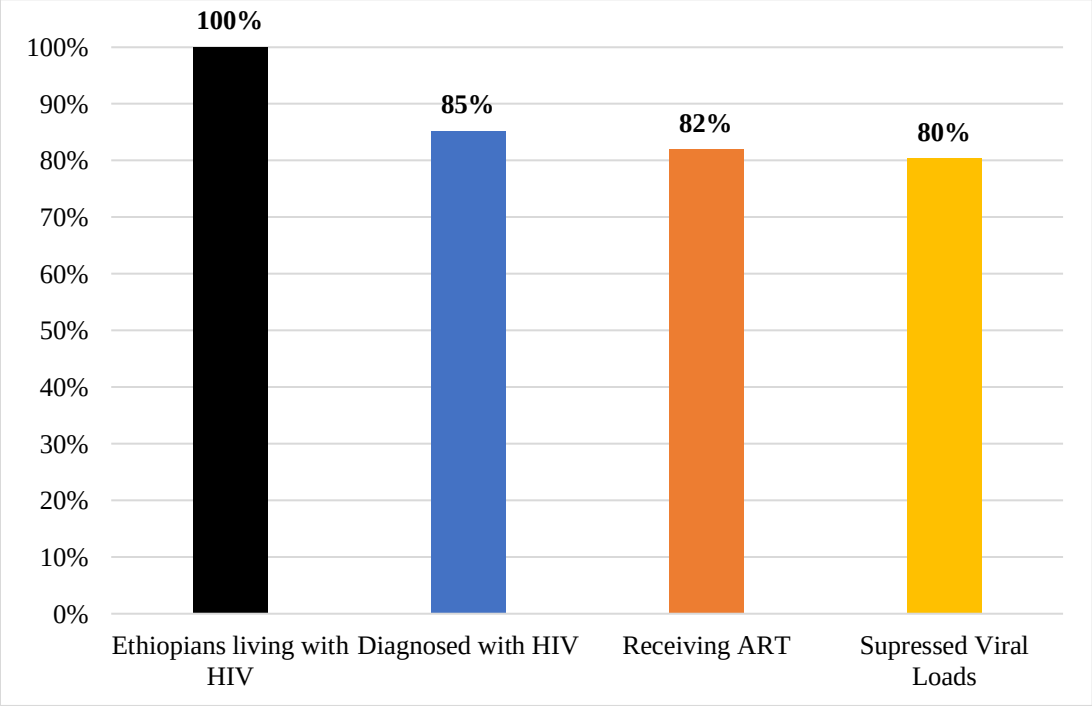


Table 1. HIV Continuum of Care Steps and Definitions[29]

HIV Continuum of Care Step	Definition
Diagnosed	The percentage of the total number of people living with HIV whose infection has been diagnosed
Linkage to Care	The percentage of people receiving a diagnosis of HIV in a given calendar year who had one or more documented CD4 or viral load tests within 30 days of diagnosis
Receipt of HIV Medical Care	The percentages of persons with diagnosed HIV who had at least one CD4 or viral load test
Retained in Care	The percentage of persons with diagnosed HIV who had two or more CD4 or viral load tests, performed at least three months apart.
Viral Suppression	Viral suppression is measured as a viral load test result of < 200 copies/mL at the most recent viral load test during measurement year.

Note. Adapted / Reprinted from Centers for Disease Control and Prevention. Understanding the HIV Care Continuum. July 2019. https://www.cdc.gov/hiv/policies/continuum.html.

B. MANUSCRIPT 1: *THRIVE WITH ME* USER ENGAGEMENT AND VIRAL SUPPRESSION IN A SAMPLE OF SEXUAL MINORITY MEN LIVING WITH HIV

B.1. Introduction

Despite numerous advancements in the HIV epidemic in the United States, it is estimated that 1.2 million people were living with HIV in 2021, of which men who have sex with men (MSM) are disproportionately affected.[1] Estimates suggest that nationally less than 5% of the United States population are considered MSM[2-4]; however, male-to-male sexual contact accounted for approximately 70% of all new infections in 2021 and 64% of persons living with HIV in 2021.[1] Among MSM, racial and ethnic minorities are also disproportionately affected. In 2021, Black/African MSM and Hispanic / Latino MSM accounted for nearly half of all new HIV diagnoses (25% and 22%, respectively) and more than 70% of all new HIV diagnoses among MSM (38% and 34%, respectively).[1]

In addition to accounting for the majority of new infections and among PLWH, MSM additionally face challenges along the HIV Continuum of Care, in particular, achieving viral suppression.[29,43] Achieving viral suppressing not only is important for the health of PLWH but has also been shown to decrease transmission to HIV negative partners.[15-18] Despite an overall increase since 2014, only 69% of all MSM living with diagnosed HIV had achieved viral suppression.[33] It is estimated that approximately 14% of MSM living with HIV are not diagnosed, and accounting for these undiagnosed

PLWH, only 59% of MSM have achieved viral suppression.[33] Racial and ethnic disparities in viral suppression are apparent among MSM. Black/African American MSM diagnosed with HIV had the lowest percentage (63%) of persons achieving viral suppression in 2021, with only 66.5% of Hispanic / Latino MSM diagnosed with HIV achieving viral suppression .[33] Achieving viral suppression is a key initiative in the United States *Ending the HIV Epidemic* goal of to reducing new infections by 90% by 2030 and to increase the percentage of diagnosed PLWH who are virally suppressed to 95%, as those who are virally suppressed or undetectable are not at risk of transmission to a seronegative partner.[18,21,31-33,35]

Use of mobile technology has grown as 85% of U.S. adults owned a smartphone in 2021 compared to only 35% in 2011.[44] This increase in technology use has created numerous opportunities for mobile health interventions targeting steps on the HIV Continuum of Care, including those aimed at improving adherence to ART and subsequent viral suppression among MSM living with HIV. According to a 2017 systematic review, numerous interventions have been utilized to target the HIV Care Continuum, of which approximately three-quarters were considered interventions aimed at improving adherence to ART.[45] However, of those adherence studies, just 2% recruited only MSM.[45] These studies utilized messages or SMS to provide daily or weekly text messages to improve ART management, reduce substance use, or reduce high risk sexual behaviors; however, results on improving viral load or adherence are mixed.[46-53] Similarly, many mHealth interventions are creating mobile apps to support ART adherence and viral suppression,[54-56] as well as other steps along the HIV

Continuum of Care, including HIV prevention, HIV testing and sexual risk reduction.[57-59] However, many of these studies are pilot or single-arm studies with no comparison groups.

According to a systematic review from 2020, there have been 16 mHealth interventions aimed at improving HIV prevention and treatment among MSM populations that utilized mHealth to deliver the intervention through 2019.[60] However, the majority of these mHealth interventions have been focused on HIV prevention (n = 13; 81%).[60] The remaining three studies utilized mHealth interventions to improve HIV treatment outcomes, most specifically medication adherence.[56,60-62] Additional studies since this systematic review have utilized mHealth interventions. These studies have included components such as (1) Self-monitoring of HIV medication and other outcomes,[54,56,61-65] (2) HIV and ART related informational content, [54,56,61,63-65] (3) Gamification features,[54,56,61,63,64]4) Tailored Messages and Feedback,[61-64] and (5) Asynchronous peer to peer exchanges.[61,63-65]

Despite the number of mHealth interventions, little is known on the effectiveness of the individual components of mHealth interventions, including use and frequency of use of these components, on HIV-related outcomes.[66-68] User engagement with mHealth interventions has been shown to be beneficial in other health-related fields, including dietary change and weight loss.[68,69] Current studies have evaluated differences among users of mHealth interventions as well as satisfaction with mHealth interventions. A 2018 study by Bonett, et al, has described patterns of user engagement with an eHealth intervention aimed at improve HIV testing among young MSM, which showed that

higher engagement was associated with older age and education and less engagement was reported among racial and ethnic minorities.[70] Additionally, a one-month pilot study among young black MSM and transgender women found that frequency of engagement or time spent on the healthMpowerment.org internet-based intervention was correlated with satisfaction with the overall intervention.[67,71] Although previous studies have evaluated the association between engagement in mHealth interventions on behavior changes,[72,73] to our knowledge, no studies to date have assessed the association with individual components of these mHealth interventions on HIV-related outcomes, in particular viral suppression. Therefore, a deeper understanding of user engagement with these mHealth intervention components is needed as well as their association on HIV-related outcomes.[74]

B.2. Methods

B.2.1 Procedures and Participants.

The Thrive with Me study (TWM) was a prospective, two-arm randomized controlled trial of *Thrive with Me*, an mHealth behavioral intervention grounded in the Information, Motivation, and Behavioral Skills Model (Figure 5).[75,76] TWM, a mobile-optimized website intervention (webapp), aimed to improve ART adherence and viral suppression among men who have sex with men (MSM) residing in the New York City (NYC) metro area.[55,65] The study protocol and participant eligibility has been previously described in full.[55,65] Eligibility criteria included 1) current male gender; 2) having sex with a man in the past year; 3) HIV-positive serostatus; 4) self-report of a detectable viral

load in the past year or ART adherence < 90% in the past two days; 5) English proficiency; 6) the ability to send / receive short message service messages; and 7) internet access over the course of the active intervention (5 months). Between October 2016 and August 2019, MSM who met the eligibility criteria were recruited and were randomized to receive the *TWM* intervention or the control arm. Participants in the intervention arm received access to the *TWM* intervention for 5-months. Participants randomized to the control arm received a weekly email with information on topics related to HIV or improving general well-being, but not specifically about ART adherence. All participants completed assessments at baseline, month-5, month-11, and month-17.

B.2.2 Thrive with Me Intervention.

Participants randomized to the intervention arm (TWM) received access to the TWM intervention for five months. The TWM intervention consisted of three primary components aimed at improving viral suppression: (1) a private social networking facilitating asynchronous peer exchanges ; (2) tailored HIV and ART adherence information; and (3) medication reminders and self-monitoring of ART adherence.[65] Those randomized to the control arm received weekly emails with HIV-relevant content for the same duration as the active intervention (5 months); however, these emails did not include information about ART adherence and were related to HIV and general health.[65] Participants were followed for up to 17-months and completed in-person assessments at the Hunter College offices in New York City. Assessments occurred at baseline (month 0), month-5, month-11, and month-17. Assessments included in-person self-reported

surveys, blood draws to measure viral load, and urine samples to detect for recent drug use. Participants received US $50 for each in-person assessment they completed. The major components of the *TWM* intervention are described below.

Asynchronous Peer Exchanges. Each participant randomized to the TWM intervention had access to a closed social networking site (only participants randomized to the TWM intervention and in the active intervention phase of the study had access) aimed at facilitating peer-to-peer interactions (Figure 6). Participants were able to post on the social networking wall (referred to as a "wallpost") as well as being able to comment on other participants wall posts ("comments"). The social networking network rules and policies are described elsewhere.[65]

HIV and ART Adherence Information. Secondly, participants randomized to the intervention received between 3 and 4 *Thrive Tips*, HIV-related content and information, each day, tied to a particular question of the Information, Motivation, and Behavioral-Skills ART Adherence Questionnaire (IMB-AAQ) (Figure 7).[77] Thrive Tips were further individualized with a blue triangle if the Thrive Tip was unique to an individual's specific adherence barriers based on their responses to the IMB-AAQ.[77] Participants were able to assess a library of all received Thrive Tips (approximately 300) throughout the course of the 5-month intervention.

Self-Monitoring of HIV-Medication. The last component of the *Thrive with Me* intervention included self-monitoring and reminders for ART medication (Figure 8). Participants were sent a SMS message at the same time each day (based on their medication timing preferences) to remind them to take their ART medications.

Participants were asked to report whether they took their medication that day either through responding through the SMS message or within the *TWM* intervention.

B.2.3 Thrive with Me Measures.

The following measures were collected during the 17-month TWM study. Unless specified, measures were collected at all assessments (baseline, month-5, month-11, and month-17).

Demographic Measures. Demographic, HIV medical history and psychosocial factors including depression, perceived stress, HIV-related stigma, social support, and life chaos were self-reported by participants at all assessment periods using a computer assisted survey instrument (CASI) via Qualtrics. Participants self-reported standard sociodemographic characteristics including age (in years), race (African American or Black; American Indian / Alaska Native; Asian; Native Hawaiian or Pacific Islander; White; or More than one race), ethnicity (Hispanic / Latino; not Hispanic / Latino), highest level of education completed (high school diploma/GED or less; some college, or an associates or technical degree; or college degree or higher); and employment status (full-time; part-time; unemployed; disabled; or retired).

Psychosocial Measures. Depressive symptoms were measured using the 10-item Center for Epidemiology Studies-Depression Scale (CESD-10), which asks participants to self-report depressive symptoms experienced in the previous seven days.[78,79] Two items were reverse code and the ten items were summed to create a total depression score (range: 0 – 30) and dichotomized to indicate those without depressive symptoms (scores

0 – 9) and those with depressive symptoms (scores $\geq$ 10).[80] Perceived stress was accessed using the 14-item Perceived Stress Scale (PSS), which asked participants to self-report how often they felt stress or thought a certain way in the previous month.[81] Perceived stress scores were categorized to low perceived stress (range: 0 – 13); moderate perceived stress (range: 14 – 26); and high perceived stress (range: 27 – 40).[81] HIV Stigma was measured using the 24-item HIV Stigma Mechanism Scale.[82,83] The 6-item internalized stigma subscale assesses the self-application of negative feelings and beliefs associated with HIV to one's self.[82] The 9-item enacted stigma subscale assesses experiences of mistreatment (discrimination, stereotyping, or prejudice) based on their HIV status.[82] The 9-item anticipated stigma subscale assesses persons' expectation of mistreatment (discrimination, stereotyping, or prejudice) due to their HIV status.[82] For each subscale, items were averaged to create a composite score (range: 1 – 5) with higher numbers indicating greater levels of stigma.[82]

The availability of social support was measured using the 19-item from the Medical Outcomes Study (MOS) Social Support Survey, including four subscales.[84] The emotional and information social support 8-item subscale assesses the degree to which a person has someone to provide advice and information, as well as a someone to confine in or listen to them.[84] The tangible support 4-item subscale assesses the degree to which a person has someone to assist them if needed.[84] The affectionate support 3-item subscale assesses the degree to which an individual has someone to show love and affection.[84] The positive social interaction 3-item subscale assesses the degree to which an individual has positive peer interactions.[84] For each of the four subscales, the items

were averaged to create a composite score for each subscale (range: 1 – 5) with higher scores indicating a greater level of social support.[84] An overall social support score was measured using the average of all self-reported items.[84] Overall life stability and predictability was measures using the 6-item Life Chaos Scale.[85] Negative items were reverse coded (items 2, 4, 5, and 6) and summed to create a composite score for life chaos (range: 6 to 30).[85]

Alcohol and Substance Use. Alcohol use was assessed using the 10-item Alcohol Use Disorders Identification Test (AUDIT), which measures frequency and behaviors of alcohol consumption, alcohol dependence, as well as issues resulting from alcohol consumptions.[86] The 10-items were summed to create a composite score (range: 0 – 40).[86] Participants were categorized into those with low risk alcohol use (scores < 7) and those with harmful or hazardous alcohol use or alcohol dependency (scores > 8).[86] Substance use was measured through a urine screening panel using the Integrated E-Z Split Key Cup II-5 panel (Innovation Laboratories).[87] The urine screening panel is able to measure use of the following drugs: THC (i.e. marijuana), methamphetamine, amphetamines, cocaine and opioids. Urine panels were able to detect use methamphetamine, amphetamines, cocaine and opioids between 1 and 4 days following use, while marijuana use can be detected for up to 30 days.[87] The five drugs were dichotomized as either no detected use and detected use. Overall drug use at each of the four assessments (excluding marijuana) was dichotomized into having no detectable level of any drug (methamphetamine, amphetamines, cocaine, and opioids) and a detectable level of cocaine, methamphetamine, amphetamines, or opioids.

ART-Related Information, Motivation, and Behavioral Skills. ART-adherence related information, motivation, and behavioral skills constructs were measured using the 33-item Information, Motivation, and Behavioral Skills ART Adherence Question (IMB-AAQ) in order to assess ART adherence strengths and barriers.[55,75-77,88,89] The 9-item information subscale measures an individuals' ART adherence-related knowledge. The 10-item motivation subscale measures both personal and social motivation for ART adherence. The 14-item behavioral skills subscale measures an individuals' ability to engage in ART adherence behaviors. Questions were asked on a 1 to 5 Likert Scale and negative items were reverse coded. Items across each subscale were summed to create composite scores for each subscale (Information Range: (9 – 45); Motivation Range: (10 – 50); Behavioral Skills Range: (14 – 70). Higher scores indicate a great amount of ART-related information, motivation, and behavioral skills.

Self-Reported Adherence to antiretroviral therapy (ART). Self-reported adherence to ART was measured using items from the Adult AIDS Clinical Trials Group.[90-93] Participants were asked "In the last 30 days, on how many days did you miss at least one dose of any of your HIV medicines and 30-day adherence was calculated by determining the percentage of ART doses taken over the past 30 days: ([30 – number missed doses]/30*100%.[90,91] Optimal adherence was dichotomized into those with low adherence (< 90% adherence in the previous 30) and those with high adherence (≥90% adherence in the previous 30 days).[94,95]

B.2.4 Viral Load.

Blood draws for viral load were performed by a certified and trained phlebotomist and analyzed by Quest Diagnostics.[65] Viral load was dichotomized at the 20 copies / mL threshold into those with undetectable viral loads (< 20 copies / mL) and those with detectable viral loads (≥ 20 copies / mL).

B.2.5 Thrive with Me User Engagement.

TWM engagement data was only collected from individuals who were randomized to receive the TWM intervention during the 5-month active intervention period. Below, we describe the categorization of the TWM components.

Overall Engagement. The number of active days engaging with the *Thrive with Me* intervention was utilized to assess overall engagement for each participant randomized to receive the intervention. The number of active days is the count of days on which the user accessed at least one screen of the *Thrive with Me* intervention. Those who did not log onto the *TWM* intervention over were categorized as (0) non-engagers with *TWM* intervention while those who accessed at least one screen of the *TWM* intervention were categorized as (1) engagers. Participants were categorized as having high and low engagement based on dichotomization at the 75th percentile. Engagement to *TWM* was categorized as the following: Non-Engagers (0 days active); Low Engagement with *TWM* (1 – 33 days active); and High Engagement to *TWM* (34+ active days).

Engagement with TWM Components. Engagement with the three *TWM* components (1. asynchronous peer exchanges; 2. HIV and ART Adherence Information; 3. Self-Monitoring of HIV medications) were measured individually. Engagement with the asynchronous peer exchanges was measured using the sum of the number of unique wall posts and comments made by a user during the *TWM* intervention. Engagement with the HIV and ART-related content was measured using the number of times users accessed the Thrive Tips. Multiple views of the same Thrive Tip were not included. Engagement with the self-monitoring of ART components was measured using the number of time users tracked their medications, regardless of whether they had taken or not taken their medication. Participants were categorized as having high and low engagement with the individual *TWM* components based on dichotomization of each component at the 75^{th} percentile.

B.2.6 Statistical Analysis

To assess engagement with the *TWM* application on viral suppression, we modelled overall engagement with the *TWM* intervention as well as engagement with the three *TWM* components on viral suppression throughout the 17-month *Thrive with Me* intervention. Viral load was dichotomized as those virally suppressed (<20 copies / mL) and those not virally suppressed ($\geq$20 copies / mL) at each time point in the study. Generalized linear models (GLM) with a binomial family and identity link with robust standard errors were utilized to estimate risk differences and 95% confidence intervals of the association of engagement with *TWM* and *TWM* components on viral suppression

throughout the 17-month intervention period. No adjustment variables were included in Model 1. The second model (Model 2) was fit to estimate risk differences adjusting for baseline viral suppression and positive urinalysis.

Lastly, we categorized individuals based on the number of *TWM* components they were considered high engagement users: No high engagement with any *TWM* components; High engagement with one *TWM* component; High engagement with two or more *TWM* components. Similar models GLM with binomial family and identity link with robust standard errors were run were run to estimate risk differences and 95% confidence intervals of the association between combined high engagement with the *TWM* components on viral suppression.

B.3. Results

B.3.1 Demographics of Thrive with Me Participants.

A total of 401 individuals participated in the *Thrive with Me* Study, of which 202 participants were randomized to receive the *Thrive with Me* intervention. A description of *Thrive with Me* study has been described previously.[65] The average age of the participants was 40 years old. More than half of participants identified as African American / Black (60.9%), with smaller proportions identifying as white (26.7%) or more than one race (5.9%). More than one-quarter of participants identified as Hispanic (30.7%). Approximately one-quarter of participants had a 4-year college, post-graduate, or professional degree (25.7%), 44.6% had attended some college or received an associates or technical degree, and 29.2% had a high school diploma or less than a high

school diploma. At baseline, 62.9% of participants had an undetectable VL and 64.9% indicated that they had optimal adherence to ART within the previous 30 days ($\geq$ 90%). One-third of participants had a positive urinalysis for methamphetamine, amphetamine, cocaine, or opioids, (32.2%) and 44.6% had a positive urinalysis for a marijuana (THC). Nearly one-third of participants had hazardous, harmful, or alcohol dependence (30.2%). A description of additional demographics of the *TWM* intervention participants is shown in Table 2.

B.3.2 Differences between TWM Users and Non-Users.

Among the 202 participants who were randomized to receive the TWM intervention, 110 participants (54.5%) accessed the TWM intervention at least once during the 5-month intervention while 92 participants did not use any of the TWM intervention components (45.5%). There were no demographic differences between users of TWM and non-users of TWM. However, at baseline, participants who used the TWM intervention were less likely to have a detectable VL (29.1%) compared to those who did not use the intervention (45.7%). TWM users were less likely to have a positive urinalysis for methamphetamine (9.1% vs 22.8%) and amphetamines (5.5% vs 20.7%) compared to those who did not use the TWM intervention.

B.3.3 Thrive with Me User Engagement.

Among the 110 participants who assessed the TWM intervention, we evaluated overall engagement, as well as the number of asynchronous peer exchanges, access to

HIV and ART informational-content, and self-monitoring of HIV medications. Descriptions of the participants user engagement with the TWM intervention are shown in Table 3.

Overall Engagement. The median number of days participants were active on *TWM* was 16 days [IQR: 5 – 33 days]. Among all participants randomized to the *TWM* intervention (n = 202), 92 had no engagement with the *TWM* intervention (45.5%), 84 were considered low engagers (41.6%) and 26 were high engagers (12.9%). Those with overall low engagement with *TWM* had a median 9 days of engagement [IRQ: 4 – 20.5] while those with high overall engagement had a median 77.5 days of engagement [IQR: 40 – 115].

Peer Exchanges. All 110 participants who were *TWM* users contributed at least one asynchronous peer exchange (wall post or comment to another user's wall post) throughout the intervention. One-hundred and ten participants contributed a wall post while three-quarters (n = 82) of participants commented on another user's wall post. The median number of asynchronous peer exchanges (wall posts and comments) per TWM engager was 7 [IQR: 2 – 34 peer exchanges] while the median number of wall posts was 3 (IQR: 1 – 13). Those with low engagement with the asynchronous peer exchanges contributed a median of 4 peer exchanges (wall posts and comments) [IQR: 2 – 9] while high engagers contributed a median of 135 peer exchanges (wall posts and comments) [IQR: 58 – 195].

Informational Content. One hundred *TWM* users accessed the informational content provided through the *TWM* intervention (*Thrive Tips)* (90.9%). The median number of *Thrive Tips* accessed was 6 [IQR: 6 – 32]. Those with low engagement with the informational content viewed a median of 4 *Thrive Tips* [IQR: 2 – 10] while those with high engagement viewed a median of 121 *Thrive Tips* [IQR: 78 – 168].

Self-Monitoring of HIV Medications. Lastly, 105 participants responded at least once to report self-monitoring of HIV medications (95.5%). The median number of self-monitoring reports was 117 days [IQR: 51 – 137]. Sixteen participants responded to the self-monitoring of HIV medications more than 95% of days. Those who were considered low engagers with the self-monitoring component contributed a median of 100 days of medication tracking [IQR: 41 – 124] while those who were high engagers contributed a median of 144.5 days [142 – 147].

B.3.4 TWM User Engagement on Viral Load.

Among those randomized to the TWM intervention, 63.2% had an undetectable viral load at baseline. Following the intervention, 58.7% of participants had an undetectable viral load at month-5, 57.4% at month-11, and 55.1% at month-17. Model results for each of the 5-month, 11-month, and 17-month time points are found in Table 4, Table 5, and Table 6.

Overall Engagement. Following the end of 5-month intervention, 73.1% of high *TWM* engagers were virally suppressed compared to 53.6% of low engagers, and 40.2%

of non-engagers. At month-5, participants who had high engagement with the *TWM* intervention were more likely to be virally suppressed compared to those who did not use the *TWM* intervention (i.e., "non-engagers") in both unadjusted (RD = 31.9; 95% CI: 12.6, 51.3), as well as adjusted models (RD = 19.4; 95% CI: 3.3, 35.5) (Table 4). Similarly, those with high engagement with the *TWM* intervention were more likely to be virally suppressed compared to those who were low engagers with the *TWM* intervention in both unadjusted (RD = 23.4; 95% CI: 4.3, 42.4) and adjusted models (RD: 17.8; 95% CI: 2.5, 33.0) (Table 4). No differences were found between engagement categories and viral suppression at month-11 (Table 5) or month-17 (Table 6).

Asynchronous Peer Exchanges. At the end of the 5-month intervention, 70.4% of high engagers with asynchronous peer exchanges were virally suppressed, 54.2% of low engagers, and 40.2% of non-engagers (Table 4). Those who were high engagers with the asynchronous peer exchanges were more likely to be virally suppressed at month-5 (RD = 25.3; 95% CI: 4.9, 45.7) and month-11 (RD = 22.5; 95% CI: 1.1, 44.0) compared to those who did not contribute asynchronous peer exchanges in unadjusted models (Table 4 and Table 5, respectively). At month-17, high engagers were more likely to be virally suppressed compared to those who did not contribute asynchronous peer exchanges (RD = 23.4; 95% CI: 2.2, 44.7) (Table 6). These results were not found among models adjusted for baseline viral suppression and positive urinalysis.

ART and HIV-Related Informational Content. Following the intervention, 68.0% of high engagers with the *Thrive Tips* were virally suppressed, 58.2% of low engagers and 44.1% of non-users were virally suppressed. There were no differences in user

engagement with the informational content and viral suppression at month-5, month-11, and month-17 in unadjusted or adjusted models (Table 4, Table 5, and Table 6).

Self-Monitoring of HIV-Medications. At the end of the 5-month intervention, 61.5% of those with high engagement, 58.2% of those with low engagement, and 40.2% of those with no engagement with the self-monitoring components of the *TWM* intervention were virally suppressed (Table 4). There were no differences in user engagement with the self-monitoring component of and viral suppression at month-5, month-11, and month-17 in unadjusted or adjusted models (Table 4, Table 5, and Table 6).

High Engagement with TWM Components. Of those randomized to receive the *TWM* intervention, 23 participants (11.4%) had high engagement with at least two of the *TWM* components, while the majority of participants (76.7%) had no high engagement with any of the three *TWM* components. In unadjusted models, following the end of the 5-month intervention, those who engaged with 2 or more *TWM* components were more likely to be virally suppressed compared to those with no high engagement (RD = 20.4; 95% CI: 0.2, 40.6) (Table 4). High engagement with multiple *TWM* components was not associated with viral suppression at any other time points or in adjusted models (Table 5, Table 6).

B.4. Discussion

This study is one of the first conducted to evaluate the role of the individual behavioral intervention components of an mHealth intervention on viral suppression

among MSM living with HIV, which has been indicated as a high priority.[74] Overall, the *Thrive with Me* intervention was not found to be associated with improved viral suppression compared to the control condition (Unpublished data). Despite this lack of evidence of an overall *TWM* intervention effect on HIV-related outcomes, there are some key findings that illustrate the association of the engagement with the individual *TWM* components on viral suppression.

First, we consider the *TWM* intervention a "light touch" intervention; it represents how users would use an mHealth intervention with little prompting from the intervention itself. Although only 55% of those who received the *TWM* intervention actively engaged with the intervention, the majority of those who were users engaged with all of the individual *TWM* components at least once. All engaged with the asynchronous peer exchanges, 91% engaged with the HIV and ART-related informational content, and 96% engaged with the self-monitoring of HIV medications component at least once during the study period.

Second, this study found that those who had high overall engagement with the *TWM* intervention were more likely to be virally suppressed compared to non-users, as well as those with low engagement at the end of the active intervention period (baseline to month-5) in both unadjusted and those models adjusting for baseline viral load and positive urinalysis. This is consistent with previous studies that have shown the largest impact of interventions immediately following the end of the active intervention period before participants no longer had access to the intervention.[54] Similarly, those with high engagement with multiple components were found to have higher proportions of viral

suppression compared to those who did not high engagement with any of the TWM components following the end of the active intervention.

Third, this study found high proportions of viral suppression among users with high engagement with the asynchronous peer exchanges in unadjusted models not only through the end of the active intervention (Month-5), but through longitudinal follow-up (Month-11 and Month-17). All participants posted at least one wall comment during the active intervention and users were also highly engaged with responding to their peers as 75% of participants responded to wall posts. A previous qualitative analysis of the asynchronous peer exchanges in TWM showed themes related to social support and HIV treatment and care, including ART adherence, HIV treatment, and healthcare.[96] Social support was the most common theme of the asynchronous peer exchanges, with half of those messages were seeking social support and half were providing social support.[96] Participants were more likely to seek emotional support, but were more likely to provide informational support.[96] In addition to social support, messages surrounding HIV treatment and care included challenges taking ART, adherence strategies, discussing HIV treatment including labs or side effects, and participants relationships with healthcare providers.[96] Asynchronous peer exchanges within "light touch" interventions may provide a source of emotional and informational support for participants in addition to providing a source of ART and HIV-related informational content to participants. However, these effects were not found after adjusting for baseline viral load and drug use; therefore, further studies are needed to understand these relationships.

Despite improvements in viral suppression among high engagers of the asynchronous peer exchanges, there was no improvement in viral suppression following the active intervention or among follow up among high engagers with the HIV and ART-related informational content or the self-monitoring of HIV medications, despite being acceptable to use among *TWM* users. These finding are similar to previously published literature that has indicated that providing information, improving knowledge about HIV or HIV treatment, or self-monitoring of HIV medications may not lead to behavioral changes or improve viral outcomes.[97]

There are limitations of this study. First, this analysis was only conducted among individuals who engaged with the *TWM* intervention, resulting in a small analytic sample of participants as only 55% of *TWM* intervention participants engaged with the mHealth intervention. Not only does this results in a small analytic sample size (n = 202), but differences were found among individuals who used the *TWM* intervention compared to those who didn't. Individuals who engaged with the intervention during the active 5-month period were more likely to have better health outcomes at baseline, including an undetectable viral load and less drug use, including methamphetamine and amphetamine, compared to those who did not engage. However, high overall engagement was associated with viral suppression at month-5 after adjusting for these. Additionally, although we collected information on frequency of engagement with each individual *TWM* components, we did not collect information on amount of time spent using the *TWM* intervention as well as the individual components. Future studies should

investigate the association of the amount of time spent engaging with the intervention and intervention components on HIV-related outcomes.

Overall, this study found key findings and possible future avenues that should be addressed when creating mHealth interventions for MSM. First, understanding the association of overall engagement with an intervention as well as the individual components on HIV-related health outcomes should be prioritized. As demonstrated in this analysis, higher overall engagement with the *TWM* intervention and high engagement with the asynchronous peer exchanges was associated with improved viral suppression up until the end of the active intervention. This study was able to evaluate engagement as the frequency of use but understanding timing of intervention use with respect to the intervention length should also be understood in future studies. Additionally, asynchronous peer exchanges were accepted by participants and were shown to be associated with improved viral suppression at all follow-up time points and may facilitate social support as well as provide ART and HIV-related informational content from peers.

Lastly, although acceptable to participants as engagement was high among *TWM* users, providing ART and HIV-related informational content and self-monitoring of HIV medications was not associated with viral suppression during follow-up. Future studies should continue to evaluate the individual components of mHealth behavioral interventions in order to better understand the association with HIV-related health outcomes.

Figure 5. Thrive with Me Intervention Components and the Information, Motivation, and Behavioral Skills Model

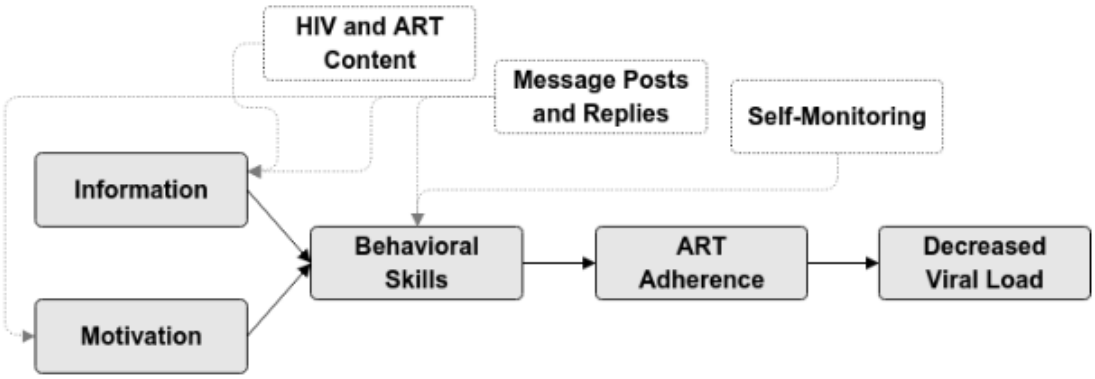


Figure 6. Thrive with Me Intervention (Asynchronous Peer Exchanges)

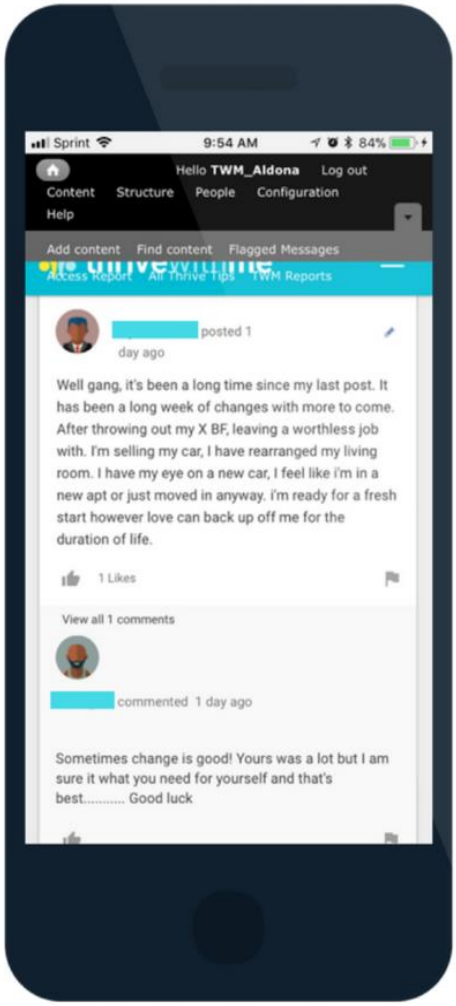


Figure 7. Thrive with Me Intervention (Thrive Tips)

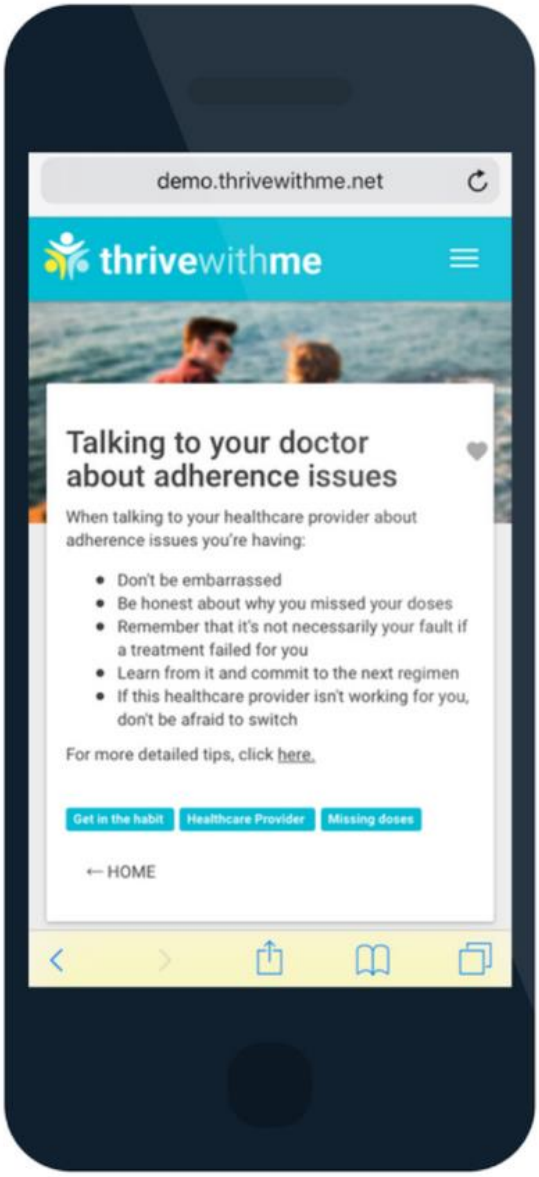


Figure 8. Thrive with Me Intervention (Self-Monitoring of HIV Medications)

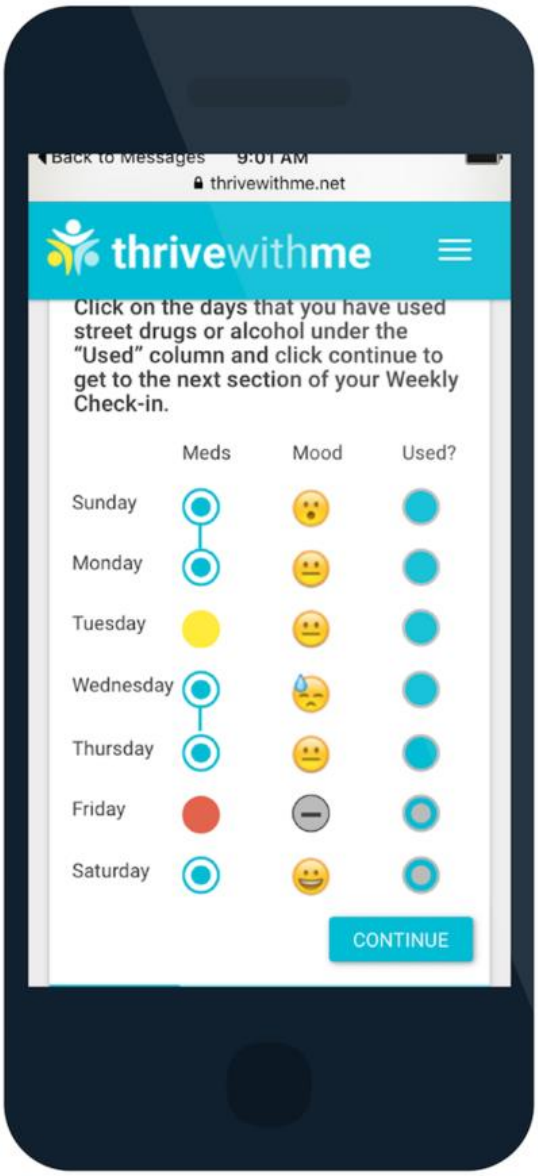


Table 2. Demographics of Thrive with Me Intervention Participants

	TWM Intervention (n = 202)	TWM Use (n = 110)	TWM No Use (n = 92)
Demographics			
Age, mean (sd)	40.1 (10.8)	40.7 (11.1)	39.3 (10.5)
Race, *% (n)*			
African American or Black	60.9 (123)	63.6 (70)	57.6 (53)
American Indian / Alaska Native	0.5 (1)	0 (0)	1.1 (1)
Asian	0.5 (1)	0.9 (1)	0 (0)
Native Hawaiian or Pacific Islander	1.0 (2)	0.9 (1)	1.1 (1)
White	26.7 (54)	25.5 (28)	28.3 (26)
More than one race	5.9 (12)	4.6 (5)	7.6 (7)
Not Reported	4.5 (9)	4.6 (5)	4.4 (4)
Hispanic, *% (n)*	30.7 (62)	31.8 (35)	29.4 (27)
Education, *% (n)*			
High School or Less	29.2 (59)	27.3 (30)	31.5 (29)
Some college / Associates / Technical Degree	44.6 (90)	45.5 (50)	43.5 (40)
College / Post-Graduate / Professional Degree	25.7 (52)	27.3 (30)	23.9 (22)
Not Reported / Missing	0.5 (1)	0 (0)	1.1 (1)
Employment Status, *% (n)*			
Full-Time	20.3 (41)	24.6 (27)	15.2 (14)
Part-Time	22.3 (45)	20.9 (23)	23.9 (22)
Unemployed	38.1 (77)	37.3 (41)	39.1 (36)
Disabled	17.3 (35)	17.3 (19)	17.4 (16)
Retired	1.0 (2)	0 (0)	2.2 (2)
Not Reported / Missing	1.0 (2)	0 (0)	2.2 (2)
HIV-Related Behaviors			
Viral Load (Biological) (< 20), *% (n)*			
Detectable VL	36.6 (74)	29.1 (32)	45.7 (42)
Undetectable VL	62.9 (127)	70.0 (77)	54.3 (50)
Not Reported	0.5 (1)	1 (0.9)	0 (0)
Optimal 30-Day Adherence (≥ 90%), *% (n)*	64.9 (131)	68.2 (75)	60.9 (56)
30-Day Adherence, *mean (sd)*	89.3 (14.5)	84.7 (22.4)	87.2 (18.6)
IMB Scale, *mean (sd)*			
Information Subscale	37.0 (5.8)	36.8 (6.1)	37.3 (5.4)
Motivation Subscale	34.8 (7.4)	34.9 (7.4)	34.8 (9.0)
Behavioral Skills Subscale	48.8 (8.3)	49.1 (7.2)	48.4 (9.4)
Drug and Alcohol Use			
Positive Urinalysis*, *% (n)*	32.2 (65)	26.4 (29)	39.1 (36)
Marijuana (THC), *% (n)*	44.6 (88)	44.6 (49)	42.4 (39)
Methamphetamine, *% (n)*	15.4 (31)	9.1 (10)	22.8 (21)
Amphetamine, *% (n)*	12.4 (25)	5.5 (6)	20.7 (19)
Cocaine, *% (n)*	16.3 (33)	16.4 (18)	16.3 (15)

	TWM Intervention (n = 202)	TWM Use (n = 110)	TWM No Use (n = 92)
Opioids, *% (n)*	1.0 (2)	1.8 (2)	0 (0)
Hazardous, Harmful Alcohol Dependence, *% (n)*	30.2 (61)	34.6 (38)	25.0 (23)
Additional Demographics			
Depressive Symptoms, *% (n)*	49.5 (100)	45.5 (50)	54.4 (50)
HIV Stigma Scale, *mean (sd)*			
Internalized Stigma	2.2 (1.1)	2.2 (1.0)	2.1 (1.2)
Anticipated Stigma	2.0 (0.9)	1.9 (0.8)	2.1 (0.9)
Enacted Stigma	1.5 (0.7)	1.4 (0.7)	1.5 (0.8)
Social Support Scale, *mean (sd)*			
Emotional Social Support	3.6 (1.2)	3.6 (1.2)	3.6 (1.2)
Affectionate Social Support	3.5 (1.3)	3.5 (1.3)	3.6 (1.4)
Tangible Social Support	3.1 (1.4)	3.1 (1.4)	3.1 (1.4)
Positive Social Interaction	3.6 (1.2)	3.6 (1.2)	3.7 (1.3)
Overall Social Support	3.5 (1.1)	3.5 (1.1)	3.5 (1.1)
HIV Life Chaos, *mean (sd)*	15.8 (4.7)	15.5 (4.3)	16.3 (5.2)
Perceived Stress, *% (n)*			
High Perceived Stress	10.9 (22)	11.8 (13)	9.8 (9)
Moderate Perceived Stress	59.4 (120)	57.3 (63)	62.0 (57)
Low Perceived Stress	29.7 (60)	30.9 (34)	28.3 (26)

*Positive urinalysis for methamphetamine, amphetamine, cocaine, or opioids

Table 3. Thrive with Me User Engagement

TWM User Engagement	Engagement with TWM Component % (n)	TWM Engaged Participants (n = 110)		Low Engagement[a]			High Engagement[a]		
		Mean (SD)	Median [IQR]	% (N)	Mean (SD)	Median [IQR]	% (N)	Mean (SD)	Median [IQR]
Number of Active Days	100 (110)	28.9 (36.9)	16 [5 – 33]	76.4 (84)	12.4 (9.8)	9 [4 – 20.5]	23.6 (26)	82.3 (41.5)	77.5 [40 –115]
Asynchronous Peer Exchanges[b]	100 (110)	41.7 (82.7)	7 [2 – 34]	75.5 (83)	7.0 (7.9)	4 [2 – 9]	24.5 (27)	152.1 (112.5)	135 [58 – 195]
Wall Posts	100 (110)	13.6 (23.5)	3 [1 – 13]	--	3.8 (4.3)	2 [1 – 5]	--	45.2 (31.2)	34.5 [20 – 68]
Comments	74.5 (82)	28.0 (64.3)	3 [0 – 12]	--	3.3 (5.0)	1 [0 – 5]	--	107.0 (96.3)	91 [29 – 142]
Informational Content	90.9 (100)	37.0 (67.3)	6 [2 – 32]	75.0 (75)	7.9 (8.9)	4 [2 – 10]	25.0 (25)	138.9 (79.5)	121 [78 – 168]
Self-Monitoring of HIV Medications	95.5 (105)	95.3 (49.9)	117 [51 – 137]	75.2 (79)	85.2 (44.7)	100 [41 – 124]	24.8 (26)	144.3 (3.11)	144.5 [142 – 147]

[a] Engagement dichotomized at the 75th percentile for each user engagement variables

[b] Excluding one individual

Table 4. Thrive with Me User Engagement on Viral Suppression (Month-5)

TWM User Engagement	TWM Intervention (n = 202) % (N)	Month – 5		
		Viral Suppression % (n)	Model 1: Risk Difference (95% CI)	Model 2: Risk Difference (95% CI)
Overall Engagement				
High Engagement	12.9 (26)	73.1 (19)	31.9 (12.6, 51.3)	19.4 (3.3, 35.5)
Low Engagement	41.6 (84)	53.6 (45)	8.5 (-7.4, 24.5)	1.6 (-12.7, 16.0)
Non-users (Ref)	45.5 (92)	40.2 (37)	Ref	Ref
Asynchronous Peer Exchanges				
High Engagement	13.4 (27)	70.4 (19)	25.3 (4.9, 45.7)	14.6 (-2.9, 32.2)
Low Engagement	41.1 (83)	54.2 (45)	10.1 (-5.9, 26.1)	2.7 (-11.6, 17.1)
Non-users (Ref)	45.5 (92)	40.2 (37)	Ref	Ref
ART and HIV-Related Content				
High Engagement	12.4 (25)	68.0 (17)	19.0 (-2.0, 40.0)	7.2 (-11.2, 25.7)
Low Engagement	37.1 (75)	52.0 (39)	3.3 (-12.7, 19.4)	-5.0 (-19.5, 9.5)
Non-users (Ref)	50.5 (102)	44.1 (45)	Ref	Ref
Self-Monitoring of ART				
High Engagement	12.9 (26)	61.5 (16)	15.4 (-6.7, 37.4)	4.4 (-17.1, 25.8)
Low Engagement	39.1 (79)	58.2 (46)	12.6 (-3.3, 28.4)	4.5 (-9.5, 18.4)
Non-users (Ref)	48.0 (97)	40.2 (39)	Ref	Ref
High Engagement to *TWM* Components				
2+ *TWM* Components	11.4 (23)	71.3 (72)	20.4 (0.2, 40.6)	10.2 (-7.5, 27.9)
1 *TWM* Components	11.9 (24)	54.2 (13)	3.3 (-19.0, 25.6)	3.2 (-19.9, 26.4)
No High Engagement	76.7 (155)	46.5 (72)	Ref	Ref

Model 1: Unadjusted

Model 2: Adjusted for baseline viral suppression and positive urinalysis

Table 5. Thrive with Me User Engagement on Viral Suppression (Month-11)

TWM User Engagement	TWM Intervention (n = 202) % (N)	Month – 11		
		Viral Suppression % (n)	Model 1: Risk Difference (95% CI)[U]	Model 2: Risk Difference (95% CI)[A]
Overall Engagement*				
High Engagement	12.9 (26)	61.5 (16)	20.3 (-2.2, 45.8)	6.8 (-13.0, 26.7)
Low Engagement	41.6 (84)	48.8 (41)	4.5 (-12.5, 21.5)	-0.6 (-15.3, 14.0)
Non-users (Ref)	45.5 (92)	34.8 (32)	Ref	Ref
Asynchronous Peer Exchanges				
High Engagement	13.4 (27)	66.7 (18)	22.5 (1.1, 44.0)	7.7 (-11.8, 27.2)
Low Engagement	41.1 (83)	47.0 (39)	3.3 (-13.9, 20.4)	-1.0 (-15.7, 13.8)
Non-users (Ref)	45.5 (92)	34.8 (32)	Ref	Ref
ART and HIV-Related Content				
High Engagement	12.4 (25)	60.0 (15)	13.9 (-8.9, 36.7)	2.1 (-15.1, 19.4)
Low Engagement	37.1 (75)	48.0 (36)	2.9 (-14.1, 19.8)	-5.2 (-21.2, 10.8)
Non-users (Ref)	50.5 (102)	37.3 (38)	Ref	Ref
Self-Monitoring of ART				
High Engagement	12.9 (26)	50.0 (13)	3.4 (-20.3, 27.1)	-6.7 (-29.8, 16.4)
Low Engagement	39.1 (79)	53.2 (42)	8.6 (-8.2, 25.5)	2.3 (-11.9, 16.5)
Non-users (Ref)	48.0 (97)	35.1 (34)	Ref	Ref
High Engagement to *TWM* Components				
2+ *TWM* Components	11.4 (23)	56.5 (13)	11.0 (-11.9, 33.9)	-0.9 (-21.3, 19.4)
1 *TWM* Components	11.9 (24)	62.5 (15)	14.2 (-7.4, 35.8)	18.2 (-5.4, 41.8)
No High Engagement	76.7 (155)	39.5 (61)	Ref	Ref

Model 1: Unadjusted

Model 2: Adjusted for baseline viral suppression and positive urinalysis

Table 6. Thrive with Me User Engagement on Viral Suppression (Month-17)

TWM User Engagement	TWM Intervention (n = 202) % (N)	Month – 17		
		Viral Suppression % (n)	Model 1: Risk Difference (95% CI)[U]	Model 2: Risk Difference (95% CI)[A]
Overall Engagement*				
High Engagement	12.9 (26)	61.5 (16)	21.2 (-1.2, 43.5)	13.7 (-7.6, 35.1)
Low Engagement	41.6 (84)	45.2 (38)	1.2 (-15.7, 18.1)	-2.7 (-18.3, 13.0)
Non-users (Ref)	45.5 (92)	35.9 (33)	Ref	Ref
Asynchronous Peer Exchanges				
High Engagement	13.4 (27)	66.7 (18)	23.4 (2.2, 44.7)	14.7 (-6.1, 35.6)
Low Engagement	41.1 (83)	43.4 (36)	-0.1 (-17.1, 16.9)	-3.1 (-18.8, 12.6)
Non-users (Ref)	45.5 (92)	35.9 (33)	Ref	Ref
ART and HIV-Related Content				
High Engagement	12.4 (25)	60.0 (15)	13.4 (-9.2, 36.0)	5.3 (-14.5, 25.0)
Low Engagement	37.1 (75)	42.7 (32)	-4.0 (-20.7, 12.9)	-12.0 (-28.5, 4.4)
Non-users (Ref)	50.5 (102)	39.2 (40)	Ref	Ref
Self-Monitoring of ART				
High Engagement	12.9 (26)	50.0 (13)	8.3 (-15.5, 32.2)	1.1 (-23.4, 25.6)
Low Engagement	39.1 (79)	50.6 (40)	7.2 (-9.5, 24.0)	3.3 (-12.0, 18.5)
Non-users (Ref)	48.0 (97)	35.1 (34)	Ref	Ref
High Engagement to *TWM* Components				
2+ *TWM* Components	11.4 (23)	56.5 (13)	14.6 (-8.3, 37.4)	7.1 (-15.4, 29.5)
1 *TWM* Components	11.9 (24)	62.5 (15)	21.0 (-0.4, 42.4)	18.6 (-1.9, 39.2)
No High Engagement	76.7 (155)	38.1 (59)	Ref	Ref

Model 1: Unadjusted

Model 2: Adjusted for baseline viral suppression and positive urinalysis

C. MANUSCRIPT 2: THE ASSOCIATION BETWEEN INDIVIDUAL AND SOCIAL LEVEL FACTORS AND PATIENT ACTIVATION AMONG A SAMPLE OF MSM LIVING WITH HIV

C.1. Introduction

It is estimated that more than 1.2 million persons in the United States were living with HIV at year-end of 2021, among whom men who have sex with men (MSM) are disproportionately represented.[1] Despite estimates suggesting MSM account for approximately 1.5% to 6% of the United States population, they account for nearly 60% of all persons living with HIV (PLWH) and more than 70% of all new infections in 2020.[1-4] In addition to being disproportionately affected by HIV diagnoses, many MSM have also not reached important thresholds along the HIV Continuum of Care, including retention in care (defined as 2 viral load or CD4 tests at least 3 months apart in one year) and viral suppression (based on the most recent viral load test.[29] It is estimated at year-end 2021 that approximately 69% of MSM with diagnosed HIV were virally suppressed and slightly more than half were considered retained in care (55%).[33]

Patient activation, defined as the behavioral skills and abilities necessary to be engaged with health care and decision making,[98-100] has been shown to improve numerous health outcomes among persons living with chronic conditions, including hypertension, diabetes, and cardiovascular disease.[101-105] Behavioral skills and engaging with health related care and decision making is crucial for persons living with HIV and may be important to reaching targets for these key stages on the HIV Continuum of Care. Management of HIV infection typically includes daily adherence to antiretroviral

medications (ART) as well as routine engagement with HIV-specific healthcare. It is important to note that this study was conducted prior to the approval of long-acting (every 2-months) ART.[28] One cross-sectional study found that increased patient activation has been shown to be associated with improved HIV outcomes including higher CD4 count, improved HIV ART adherence, and viral suppression among a population of both males and females living with HIV.[106]

Understanding the factors, including both the individual-level and social-level factors that influence patient activation among PLWH, may be important to improving HIV-related health outcomes including viral suppression and retention in care. Previous studies have evaluated the impact of individual-level factors on patient activation and found that advanced education, increased social status, were associated with an increase in patient activation while problematic alcohol use and depression were associated with a decrease in patient activation among a sample of PLWH.[106,107] Social-level factors are measures that evaluate how an individual's social structure may impact an individual and include factors such as social support, social isolation, and stigma.[108] However, only one such study has evaluated the association between both individual-level factors and social-level factors on patient activation. A study among a sample of black women living with HIV in the Southern United States found that anticipated and enacted stigma were inversely associated with patient activation while resilience and social support were positively associated with patient activation.[109] However, no such study has evaluated the impact of social-level factors on a sample of MSM living with HIV. Additionally, no study to our knowledge has evaluated the impact of recent drug use (confirmed through

urinalysis) on patient activation. Marshall et al evaluated the association between self-reported drug use (Addiction Severity Index) and patient activation.[106]

This study plans to expand upon the current literature to evaluate additional individual-level and social-level factors that may be associated with patient activation. These factors include individual-level factors such as ART-related information, motivation, and behavioral-skills, recent drug use (confirmed through urinalysis), life chaos, perceived stress, depression, and alcohol use, and social-level factors including social support and HIV-related stigma and will be the first of our knowledge to evaluate these individual-level and social-level factors and their association with patient activation among a sample of MSM living with HIV.

C.2. Methods

C.2.1 Procedures and Participants

The Thrive with Me (TWM) study was a prospective, two-arm randomized controlled trial of the TWM intervention, an mHealth intervention grounded in the Information, Motivation, and Behavioral Skills model (IMB).[75,76] *TWM*, a mobile-optimized website intervention (webapp), was aimed to improve ART adherence and viral suppression among MSM residing in the New York City (NYC) metro area.[55,65] The study protocol and participant eligibility has been previously described in full.[55,65] Eligibility criteria included 1) current male gender; 2) having sex with a man in the past year; 3) HIV-positive serostatus; 4) self-report of a detectable viral load in the past year or ART adherence < 90% in the past two days; 5) English proficiency; 6) the ability to

send / receive short message service messages; and 7) internet access over the course of the active intervention (5 months).[55,65] Between October 2016 and August 2019, MSM who met the eligibility criteria were randomized to receive the *TWM* intervention or the control arm. Participants in the intervention arm received access to the *TWM* intervention for 5-months. Participants randomized to the control arm received a weekly email with information on topics related to HIV or improving general well-being, but not specifically about ART adherence. All participants completed assessments at baseline, month-5, month-11, and month-17.

C.2.2 Measures.

The following measures were collected during the 17-month *TWM* study. Unless specified, each measure was collected at all assessments (baseline, month-5, month-11, and month-17) using a CASI-survey via Qualtrics.

Demographic Measures. Participants self-reported sociodemographic characteristics including age, race (African American or Back; American Indian or Alaska Native; Asian; Native Hawaiian or Pacific Islander; White; or more than one race), ethnicity (Hispanic / Latino; not Hispanic / Latino), highest level of education (high school diploma / GED or less; some college or completing an associates or a technical degree; or college degree or higher); and employment status (full-time; part-time; unemployed; disabled; or retired).

Viral Load and Adherence Measures. Blood draws for viral load were performed by a certified and trained phlebotomist and analyzed by Quest Diagnostics.[65] Viral load

was dichotomized at the 20 copies / mL threshold into those with undetectable viral loads (< 20 copies / mL) and those with detectable viral loads (≥ 20 copies / mL). Self-reported adherence to ART was measured using items from the Adult AIDS Clinical Trials Group.[90-93] Participants were asked "In the last 30 days, on how many days did you miss at least one dose of any of your HIV medicines and 30-day adherence was calculated by determining the percentage of ART doses taken over the past 30 days: ([30 – number missed doses] / 30) *100%.[90,91] Optimal adherence was dichotomized into those with low adherence (< 95% adherence in the previous 30) and those with high adherence (≥95% adherence in the previous 30 days).[94,95]

Individual-Level Factors. ART-adherence related information, motivation, and behavioral skills constructs were measured using the 33-item Information, Motivation, and Behavioral Skills ART Adherence Question (IMB-AAQ) in order to assess ART adherence strengths and barriers.[55,75-77,88,89] The 9-item information subscale measures an individuals' ART adherence-related knowledge. The 10-item motivation subscale measures both personal and social motivation for ART adherence. The 14-item behavioral skills subscale measures an individuals' ability to engage in ART adherence behaviors. Questions were asked on a 1 to 5 Likert Scale and negative items were reverse coded. Items across each subscale were summed to create composite scores for each subscale (Information Range: 9 – 45; Motivation Range: 10 – 50; Behavioral Skills Range: 14 – 70. Higher scores indicate a great amount of ART-related information, motivation, and behavioral skills related to ART adherence. ART-related information,

motivation, and behavioral skills were categorized into low, medium, and high categories based on the 33rd and 67th percentile.

Alcohol use was assessed using the 10-item Alcohol Use Disorders Identification Test (AUDIT), which measures frequency and behaviors of alcohol consumption, alcohol dependence, as well as issues resulting from alcohol consumptions.[86] The 10-items were summed to create a composite score (range: 0 – 40).[86] Participants were categorized into those with low risk alcohol use (scores < 7) and those with harmful or hazardous alcohol use or alcohol dependency (scores > 8).[86]

Substance use was measured through a urine screening panel using the Integrated E-Z Split Key Cup II-5 panel (Innovation Laboratories),[87] which was found to have excellent sensitivity (100%) and specificity (100%).[110] The urine screening panel is able to measure use of the following drugs: THC (i.e. marijuana), methamphetamine, amphetamines, cocaine and opioids. Urine panels were able to detect use of methamphetamine, amphetamines, cocaine and opioids between 1 and 4 days following use, while marijuana use can be detected for up to 30 days following use.[87] Each of the five individual drugs were dichotomized as either no detected use and detected use. An overall drug use variable (excluding marijuana) was created at each of the four assessments indicating having no detectable level of any drug use (methamphetamine, amphetamines, cocaine, and opioids) or a detectable level of either cocaine, methamphetamine, amphetamines, or opioids.

Depressive symptoms were measured using the 10-item Center for Epidemiology Studies-Depression Scale (CESD-10), which asks participants to self-report depressive

symptoms experienced in the previous seven days.[78,111] Two items were reverse coded and then summed to create a total depression score (range: 0 – 30) and dichotomized to indicate those without depressive symptoms (scores 0 – 9) and those with depressive symptoms (scores $\geq$ 10).[80] Perceived stress was accessed using the 14-item Perceived Stress Scale (PSS), which asked participants to self-report how often they felt stress or thought a certain way in the previous month.[81] Perceived stress scores were categorized to low perceived stress (Range: 0 – 13); moderate perceived stress (range: 14 – 26); and high perceived stress (range: 27 – 40).[81] Overall life stability and predictability was measured using the 6-item Life Chaos Scale.[85] Negative items were reverse coded (items 2, 4, 5, and 6) and summed to create a composite score for life chaos (range: 6 to 30).[85] Life chaos scores were categorized into low, medium, and high categories based on the 33rd and 67th percentile.

Social-Level Factors. In addition to individual-level factors, the association between two social-level factors and patient activation were evaluated: HIV stigma and social support. HIV stigma was measured using the 24-item HIV Stigma Mechanism Scale.[82,83] The 6-item internalized stigma subscale assesses the self-application of negative feelings and beliefs associated with HIV to one's self.[82] The 9-item enacted stigma subscale assesses experiences of mistreatment (discrimination, stereotyping, or prejudice) based on their HIV status.[82] The 9-item anticipated stigma subscale assesses person' expectation of mistreatment (discrimination, stereotyping, or prejudice) due to their HIV status.[82] For each subscale, items were averaged to create a composite score (range: 1 – 5) with higher numbers indicating greater levels of stigma.[82] Internalized,

anticipated and enacted HIV-stigma levels were categorized into low, medium, and high levels of stigma based on the 33rd and 67th percentile.

The availability of social support was measured using the 19-items from the Medication Outcomes Study (MOS) Social Support Survey, including four subscales.[84] The emotional / information social support 8-item subscale assesses the degree to which a person has an individual to provide advice and information, as well as someone to confide in or listen to them.[84] The tangible support 4-item subscale assesses the degree to which a person has someone to assist them if needed.[84] The affectionate support 3-item subscale assesses the degree to which an individual has someone to show them love and affection.[84] The positive social interaction 3-item subscale assesses the degree to which an individual has positive peer interactions.[84] For each of the four subscales, the items were averaged to create a composite score for each subscale (range: 1 – 5) with higher scores indicating a great level of social support.[84] An overall social support score was measured using the average of all self-reported items.[84] Each social support subscale and overall social support were categorized into low, medium, and high levels of social support based on the 33rd and 67th percentile.

C.2.3 Patient Activation Measure.

Participants were asked about their individual patient activation at the Month-11 and Month-17 assessments using the 13-item Patient Activation Measure.[98-100] This measure assesses an individual's underlying knowledge, skills, and confidence to manage his or her own health and healthcare.[100] Participants were asked how much they agree or

disagree with each of the 13-statements on a 4 point Likert scale: Disagree strongly (1), disagree (2), agree (3), and agree strongly (4). Example statements include: "I am confident I can help prevent or reduce problems associated with my health," "I understand my health problems and what causes them", and "I am confident I can figure out solutions when new problems arise with my health." In order to be scored, participants had to answer 10 out of 13 questions. Data collected during the 11-month and 17-month assessment periods were scored using a proprietary scoring algorithm (Range: 0 – 100), with higher scores indicating greater patient activation (Table 7).[100] Participants who did not complete the assessment were considered missing. Patient activations levels were categorized into the following based on their numeric score: Level 1 (Disengaged and overwhelmed); Level 2 (Becoming aware, but still struggling); Level 3 (Taking action); Level 4 (Maintaining behaviors and pushing further). For subsequent descriptive summaries, Level 1 and Level 2 were combined due to small numbers.

C.2.4 Statistical Analysis.

Demographic and HIV-related measures were calculated for participants at baseline as well as for those who were retained at the month-11 survey point. We evaluated differential loss-to-follow up by examining differences between those retained at the month-11 survey and those not retained were evaluated using t-tests for continuous variables and chi-square tests for categorical variables. Demographics and HIV-related

statistical summaries were calculated for each Patient Activation Level for the 324 participants retained at month-11.

To estimate the association of individual-level and social-level factors on patient activation, we modeled each individual-level and social-level factor with the patient activation measure. Generalized Linear Models (GLM) with a normal family, identity link, and robust standard errors were utilized to estimate risk differences and 95% confidence intervals of the association of individual and social level characteristics on patient activation at month-11. Two models were run for each of the individual-level and social-level factors and their association with patient activation: (1) unadjusted models evaluating the association between each factor and patient activation; (2) a model adjusting for the TWM intervention, baseline viral suppression, age, race, ethnicity, and education.

C.3. Results

C.3.1 Demographics of Thrive with Me Participants.

A total of 401 participants were recruited to participant in the TWM study. At month-11, a total of 328 participants were retained (82% of the study sample). On average, participants were 39 years old. More than half of the participants identified as Black or African American (57.0%), with smaller proportions identifying as white (27.7%) or more than one race (8.5%). Approximately one quarter of participants identified as Hispanic or Latino (27.7%). Three-quarters of participants had completed some college or higher at the beginning of the study (77.4%), and equal numbers of

participants worked either full-time or part-time (43%) or were unemployed (41%). At month-11, 61% of participants had undetectable viral loads and less than half of participants were considered to have optimal adherence (48%). Those who were not retained at month-11 were more likely to have baseline detectable viral loads (53.4%) compared to those who were retained (38.4%). The average adherence of participants at month-11 was 88%.

C.3.2 Patient Activation Measures.

At month-11, of the 328 participants retained, patient activation measures were collected and calculated for 324 participants (98.7%). On average, participants in the study had a patient activation score of 74, indicating that they were considered Level 3 of 4 for patient activation: "taking action." Nearly half of participants were considered Level 4, indicating they were "maintaining their behaviors and pushing forward," while 37% were considered Level 3, indicating they were "taking action." Fewer than 15% were considered Level 2 (Becoming aware, but still struggling) or Level 1 (Disengaged and overwhelmed). Additional demographic and HIV-related characteristics by patient activation levels are found in Table 9.

C.3.3 Individual-Level Characteristics and Patient Activation.

The association between individual-level characteristics and patient activation are described in Table 10. At month-11, the average information, motivation, and behavioral skills values were as follows, indicating moderate to higher levels of information,

motivation, and behavioral skills among this population: information (37.7, range: 9 – 45), motivation (34.9; range: 9 - 45), and behavioral skills (49.9; range: 14 - 70). ART-related Information, Motivation, and Behavioral Skills were all associated with an increase in patient activation in both unadjusted (Model 1) and adjusted (Model 2) models. Adjusting for randomization, baseline viral load, age, race, ethnicity, and education, individuals with high (RD = 17.9; 95% CI: 13.3, 22.6) or medium (RD = 13.5; 95% CI: 9.3, 17.3) levels of ART-related information had increased patient activation measure levels. Similar results were found for ART-related high motivation (RD = 15.3; 95% CI: 11.0, 19.7) and medium motivation (RD = 3.6; 95% CI: -0.8, 8.0) as well as high behavioral skills (RD = 25.0; 95% CI: 21.3, 28.7) and medium behavioral skills (RD = 14.8; 95% CI: 10.9, 18.7).

Nearly one-third of participants retained at month-11 were considered drug users (i.e. positive for methamphetamine, amphetamine, cocaine, or opioids) by urinalysis (n=97), while 43% had a positive urinalysis for marijuana. Less than 20% of participants used methamphetamine, amphetamine, cocaine, or opioids. Overall, having a positive urinalysis resulted in a 3.1 unit decrease in patient activation compared to those who tested negative (95% CI: -7.4, 1.2). Stronger but less precise results were found among individuals with positive urinalyses for methamphetamine (RD = -5.2; 95% CI: -10.0, -0.4), and amphetamine (RD = -4.3; 95% CI: -9.9, 1.3). Alternatively, marijuana use was associated with an increase in patient activation (RD = 3.6; 95% CI: -0.6, 7.9). There is less evidence to suggest an association between cocaine and opioid use on patient

activation. Those with hazardous or harmful alcohol had a patient activation score 4.7 units lower than individuals who did not (95% CI: -9.6, 0.1).

Additional individual-level measures including depression, life chaos, and perceived stress were evaluated for their association with patient activation. Individuals with depressive symptoms had patient activations scores 12.7 points lower compared to those without depressive symptoms (95% CI: -16.6, -8.8). Individuals with medium or high perceived stress had patient activation scores 11.3 units (95% CI: -15.3, -7.3) and 22.4 units (95% CI: -29.1, -15.7) lower compared to those with low perceived stress. Those with high or medium life chaos had patient activation scores 15.1 units (95% CI: -19.8, -10.5) and 9.0 units (95% CI: -13.4, -4.7) lower compared to those with low life chaos.

C.3.4 Social-Level Characteristics and Patient Activation.

In addition to individual level variables, this analysis evaluated two social-level variables and their subscales and the association with the patient activation measure, HIV-related stigma, and social support (Table 11). Overall, individuals in this study experienced medium to low levels of HIV-related stigma (range: 1 – 5): internalized (mean = 2.1, sd = 1.1), anticipated (mean = 1.9, sd = 0.9), and enacted (mean = 1.5, sd = 0.7). Internalized, anticipated, and enacted HIV stigma were inversely associated with patient activation in both unadjusted and adjusted models. In adjusted models, those with high or medium levels of internalized stigma had patient activation scores 11.2 units (95% CI: -15.8, -6.6) and 5.5 units (95% CI: -10.0, -1.0) lower compared to those with

low internalized stigma. Similar results were found for those with high and medium anticipated stigma as well as high and medium enacted stigma (Table 11).

Alternatively, social support was positively associated with patient activation. In adjusted models, those with high levels of emotional support had patient activation values 14.9 units higher than those with low emotional support (95% CI: 10.6, 19.3). Similar results were found between high affectionate (RD = 15.2; 95% CI: 10.9, 19.5) and medium affectionate (RD = 5.2; 95% CI: 0.7, 9.6) social support compared to low affectionate social support, as well as high tangible (RD = 16.9; 95% CI: 12.3, 21.5) and medium tangible (RD = 5.1; 95% CI: 0.7, 9.4) social support compared to low tangible social support. Those with high social interaction had patient activation level 12.5 units higher (95% CI: 8.4, 16.6) compared to those with low social interaction. Individuals with overall high social had patient activation measures 15.0 units higher (RD = 10.8, 19.3) than those with low overall social support.

C.4. Discussion

This analysis expanded upon the current literature by evaluating the association of several individual and social level factors and their associations with the patient activation measure among a sample MSM living with HIV enrolled in the *TWM* intervention. Overall, individuals in this study had high levels of patient activation; more than 85% of the participants in the study were considered to have high levels (Level 3 – 4) of patient activation, indicating they were either maintaining their behaviors (Level 4) or taking action to improve their behaviors (Level 3). Less than 15% were considered to

have lower levels of patient activation (Level 1 – 2), indicating that they were either disengaged or struggling with their health or healthcare. Although high, the mean patient activation measure value was found to be similar to previously published studies among PLWH and other chronic conditions.[101,106,107,112,113] The average patient activation measure for the general population was 61.9 and averages ranged from 54.3 among individuals with self-rated poor health to 68.7 among individuals with self-rated excellent health.[98] Therefore, even among individuals with in the present study who either had self-described suboptimal adherence or a detectable viral load in the previous year, individuals living with HIV or other chronic conditions may have better patient activation compared to the general population. Similarly, individuals who engage with research studies may not be representative of the general population's patient activation. Authors have suggested collapsing Levels 1 and 2 and to add items to the upper end of the scale to address higher patient activation levels among individuals with chronic conditions.[114]

Additionally, patient activation measures were collected more than half-way through the *TWM* intervention, with adequate retention at month-11 (82%). Baseline viral suppression was the only known difference between those retained and those lost to follow-up. However, there may be some unknown factors associated with being retained in care and patient activation. Among the 324 participants retained at month-11, an additional 24 participants were lost to follow-up at month-17. Compared to those retained at month 17, mean patient activation was nearly 10-units higher than those not retained (75.0 vs 65.5). Those retained in the present study at month-11 in may have higher levels of patient activation than those who were lost to follow up by the month-11

assessment, which may lead to an overestimate of patient activation in this sample. Participants in the *TWM* study also received up to five months of the *TWM* intervention, which included ART-related information, asynchronous peer exchanges, and self-monitoring of ART, while the control group received weekly emails with information about HIV and general well-being, which may have increased patient activation.

This is the first to our knowledge to evaluate the association of ART-related information, motivation, and behavioral skills and patient activation among a sample of PLWH. Having high or medium levels of ART-related information, motivation, and behavioral skills was associated with an increased patient activation. Although this relationship has not been evaluated previously, ART-related information, motivation, and behavioral skills has been found to be associated with other HIV-related behaviors and outcomes.[88,89]

In addition to the IMB-AAQ, this study is the first to evaluate recent drug use as confirmed by urinalysis for five illicit drugs and patient activation. Less than one-third of our study population were drug users (positive for methamphetamine, amphetamine, cocaine, or opioids) while approximately 40% used marijuana. Recent methamphetamine and amphetamine use were found to decrease patient activation while marijuana use may be associated with increased patient activation. This differs from the previous study among PLWH which found no association between self-reported drug use and patient activation.[106] Previous studies have evaluated the association between stimulant use and decreased ART adherence and viral suppression.[115-118] However, marijuana use was found to be associated with increased patient activation. It is estimated that 77% of

PLWH will use marijuana in their lifetime. No study to our knowledge has evaluated the association between marijuana use and patient activation, but the relationship between marijuana use and other HIV-related outcomes are mixed.[119] One potential hypothesis for this result is that methamphetamine, amphetamine, cocaine, and opioids are only able to be detected within 4 days of use, indicating more acute drug use, whereas marijuana use is able to be detected for up to 30 days following use.[87] Hazardous or harmful alcohol use was found to decrease patient activation, which is similar to previous studies.[106] In addition to drug use, having high or medium levels of perceived stress, depressive symptoms, and life chaos were associated with lower patient activation, which are consistent with previous studies.[106,120,121]

At the social level, both HIV-related stigma and social support were found to be associated with patient activation, which supports the results of a previous study that stigma was inversely associated with patient association while social support was positively associated with patient activation among a sample of black women living with HIV.[109] Additionally, previous studies among chronic diseases including coronary heart disease and chronic pain found a positive relationship between social support and patient activation.[122-125] One study identified an inverse relationship between stigma and patient activation among persons with type 2 diabetes.[126]

This study does have some limitations that must be addressed. First, this analysis was based on a subset of participants of a larger randomized control trial at a third time-point in the study. Overall, retention at the month-11 time point was adequate (82%) and adjustments were made for differences in those retained and not retained, selection bias

due to loss-to follow-up differences between those retained and not retained may be apparent. As discussed, among participants retained at the last survey point, patient activation values were nearly 10 units lower among individuals who were lost to follow-up between month-11 and month-17 and those were retained at month-17.

Similarly, although consistent with previous studies of patient activation, participants in this study were considered to have high levels of patient activation, indicating that they were highly motivated and already engaged in their medical care.[101,106,107,112,113] Nearly half of participants were considered to have the highest level of patient activation at month-11. However, we are unable to determine if being a participant in the research study, either being in the intervention arm or control arm, could have impacted patient activation. Therefore, individuals in this study may have an overestimate of patient activation compared to the general population of MSM living with HIV. In order to account for these limitations, future studies evaluating patient activation should ensure that patient activation measures are collected at baseline as well as all subsequent time points.

Further research can expand upon the limitations of this study to better understand patient activation as well as the role of individual-level and social-level factors on patient activation. First, it is important to evaluate patient activation among the general population of MSM living with HIV, including individuals not engaged in HIV care or those in research studies, to better estimate patient activation among this population. Among these populations, future studies evaluating the individual-level and social-level

factors and their association with patient activation may more accurately describe these relationships among all persons living with HIV.

Table 7. Patient Activation Measures[100]

Patient Activation Measure	Score Range
Level 1: Disengaged and overwhelmed	0 – 47
Level 2: Becoming aware, but still struggling	47.1 – 55.1
Level 3: Taking action	55.2 – 75
Level 4: Maintaining behaviors and pushing further	75.1 – 100

Table 8. Comparison of Thrive with Me Participants Retained at Month-11

	TWM Population N = 401	Month-11	
		Retained N = 328 (82%)	Lost to Follow-Up N = 73 (18%)
Demographics (Baseline)			
Age, *mean (sd)*	39.1 (10.8)	39.3 (10.9)	37.9 (10.1)
Race, *% (n)*			
White	28.2 (113)	27.7 (91)	30.1 (22)
Black or African American	57.4 (230)	57.0 (187)	58.9 (43)
American Indian / Alaska Native	1.3 (5)	1.5 (5)	0 (0)
Asian	0.8 (3)	0.9 (3)	0 (0)
Native Hawaiian or Other	0.5 (2)	0.6 (20)	0 (0)
More than one race	7.7 (31)	8.5 (28)	4.1 (3)
Unknown / Not Reported	4.2 (17)	3.7 (12)	6.8 (5)
Ethnicity, *% (n)*			
Hispanic / Latino	26.9 (108)	27.7 (91)	23.3 (17)
Not Hispanic / Latino	72.3 (290)	71.7 (235)	75.3 (55)
Missing	0.8 (3)	0.6 (2)	1.4 (1)
Education, *% (n)*			
High School or Less	24.3 (97)	22.6 (74)	31.5 (23)
Some college / Associates Degree	41.7 (167)	41.6 (136)	42.5 (41)
College / Postgraduate	34.0 (136)	35.8 (117)	26.0 (19)
Employment Status, *% (n)*			
Full Time	21.7 (87)	21.3 (70)	23.3 (17)
Part Time	22.0 (88)	21.7 (71)	23.3 (17)
Disabled	15.7 (63)	14.3 (47)	21.9 (16)
Retired	0.8 (30)	0.9 (3)	0 (0)
Unemployed	38.9 (156)	40.9 (134)	30.1 (22)
Missing	1.0 (4)	0.9 (3)	1.4 (1)
HIV-Related Measures (Baseline)			
Viral Load, *% (n)*			
Detectable	38.4 (156)	36.6 (120)	53.4 (39)
Undetectable	61.3 (246)	63.1 (207)	46.6 (34)
Missing	0.3 (1)	0.3 (1)	0 (0)
Adherence, *% (n)*			
Optimal ($\geq$ 95)	42.9 (172)	42.4 (139)	45.2 (33)
Suboptimal (< 95)	57.1 (229)	57.6 (189)	54.8 (40)
Adherence (%), *mean (sd)*	87.6 (17.6)	87.4 (18.2)	88.8 (15.1)
IMB Scale *mean (sd)*			
Information	36.7 (5.8)	36.6 (5.9)	37.1 (5.7)
Motivation	34.0 (8.4)	34.0 (8.3)	34.3 (8.7)
Behavior	48.2 (8.5)	48.1 (8.5)	48.6 (8.8)

Table 9. Demographics by Patient Activation Levels among Thrive with Me Participants at Month-11

Variable	Level 4[a] N = 156 (48%)	Level 3[b] N = 120 (37%)	Levels 2 & 1[c] N = 48 (15%)	Total N = 324
Demographics				
Age, *mean (sd)*	38.4 (10.2)	40.8 (11.8)	39.2 (10.8)	39.4 (10.9)
Race, *% (n)*				
White	19.9 (31)	33.3 (40)	41.7 (20)	27.7 (91)
Black or African American	67.3 (105)	38.3 (58)	45.8 (22)	57.0 (187)
American Indian / Alaska Native	0.6 (1)	2.5 (3)	0 (0)	1.5 (5)
Asian	1.3 (2)	0 (0)	2.1 (1)	0.9 (3)
Native Hawaiian or Other	0.6 (1)	0.8 (1)	0 (0)	0.6 (2)
More than one race	7.7 (12)	10.0 (12)	6.3 (3)	8.5 (28)
Unknown / Not Reported	2.6 (5)	5.0 (6)	4.2 (2)	3.7 (12)
Ethnicity, *% (n)*				
Hispanic / Latino	25.6 (40)	27.5 (33)	35.4 (17)	27.7 (91)
Not Hispanic / Latino	73.7 (116)	71.7 (86)	64.6 (31)	71.7 (235)
Missing	0.6 (1)	0.8 (1)	0 (0)	0.6 (2)
Education, *% (n)*				
High School or Less	25.6 (40)	16.7 (20)	22.9 (11)	22.6 (74)
Some college / Associates Degree	44.9 (70)	40.0 (48)	37.5 (18)	41.6 (136)
College / Postgraduate	29.5 (46)	43.4 (52)	37.5 (18)	35.8 (117)
Employment Status, *% (n)*				
Full Time	21.8 (34)	23.3 (28)	16.7 (8)	21.3 (70)
Part Time	20.5 (32)	22.5 (27)	25.0 (12)	21.7 (71)
Disabled	14.7 (23)	15.0 (18)	12.5 (6)	14.3 (47)
Retired	0.6 (1)	1.7 (2)	0 (0)	0.9 (3)
Unemployed	41.7 (65)	37.5 (45)	43.8 (21)	40.9 (134)
Missing	0.6 (1)	0 (0)	2.1 (1)	0.9 (3)
HIV-Related Measures (Month-11)				
Viral Load, *% (n)*				
Detectable	38.5 (60)	33.3 (40)	47.9 (23)	38.4 (126)
Undetectable	60.9 (95)	65.8 (79)	50.0 (24)	60.7 (199)
Missing	0.6 (1)	0.8 (1)	2.1 (1)	0.9 (3)
Adherence, *% (n)*				
Optimal ($\geq$ 95)	55.1 (86)	44.2 (53)	33.3 (16)	47.6 (156)
Suboptimal (< 95)	44.9 (70)	55.8 (67)	66.7 (32)	52.4 (172)
Adherence (%), *mean (sd)*	90.1 (18.8)	88.0 (18.3)	80 (29.4)	87.8 (20.6)

[a] Maintaining behaviors and pushing further

[b] Taking action

[c] Disengaged and overwhelmed (Level 1) or Becoming aware, but still struggling (Level 2)

Table 10. Individual-Level Associations with Patient Activation Measure

Variable	Model 1[a] RD (95% CI)	Model 2[b] RD (95% CI)
Information (IMB-AAQ)		
High	18.4 (13.9, 22.8)	17.9 (13.3, 22.6)
Medium	13.5 (9.3, 17.7)	13.5 (9.3, 17.3)
Low	*Ref*	*Ref*
Motivation (IMB-AAQ)		
High	15.8 (11.4, 20.2)	15.3 (11.0, 19.7)
Medium	4.4 (0.2, 8.8)	3.6 (-0.8, 8.0)
Low	*Ref*	*Ref*
Behavioral Skills (IMB-AAQ)		
High	24.3 (20.6, 28.1)	25.0 (21.3, 28.7)
Medium	14.3 (10.3, 18.2)	14.8 (10.9, 18.7)
Low	*Ref*	*Ref*
Drug Use		
Positive Urinalysis	-3.3 (-5.6, 0.9)	-3.1 (-7.4, 1.2)
Any Marijuana Use	5.3 (1.4, 9.2)	3.6 (-0.6, 7.9)
Methamphetamine	-5.9 (-10.6, -1.2)	-5.2 (-10.0, -0.4)
Amphetamine	-5.9 (-11.4, -0.3)	-4.3 (-9.9, 1.3)
Cocaine	1.1 (-5.2, 7.5)	0.1 (-6.4, 6.6)
Opioid	-0.9 (-10.2, 8.4)	3.8 (-7.5, 15.0)
Hazardous, Harmful Alcohol Use	-4.6 (-9.2, -0.1)	-4.7 (-9.6, 0.1)
Depressive Symptoms	-12.5 (-16.2, -8.8)	-12.7 (-16.6, -8.8)
Life Chaos		
High	-14.2 (-18.9, -9.5)	-15.1 (-19.8, -10.5)
Medium	-8.8 (-13.2, -4.5)	-9.0 (-13.4, -4.7)
Low	*Ref*	*Ref*
Perceived Stress		
High	-21.8 (-28.6, -14.9)	-22.4 (-29.1, -15.7)
Medium	-10.9 (-14.7, -6.7)	-11.3 (-15.3, -7.3)
Low	*Ref*	*Ref*

[a] Model 1: Unadjusted model

[b] Model 2: Adjusted for intervention, baseline viral load, age, race, ethnicity, and education

*Positive urinalysis for methamphetamine, amphetamine, cocaine, or opioid

Table 11. Social-Level Associations with Patient Activation

Variable	Model 1[a] RD (95% CI)	Model 2[b] RD (95% CI)
Internalized HIV Stigma		
High	-11.4 (-15.9, -6.8)	-11.2 (-15.8, -6.6)
Medium	-5.4 (-10.0, -0.8)	-5.5 (-10.0, -1.0)
Low	*Ref*	*Ref*
Anticipated HIV Stigma		
High	-14.6 (-19.2, -10.1)	-14.7 (-19.2, -10.1)
Medium	-7.0 (-11.3, -2.7)	-6.0 (-10.4, -1.7)
Low	*Ref*	*Ref*
Enacted HIV Stigma		
High	-9.3 (-13.8, -4.9)	-9.0 (-13.5, -4.4)
Medium	-6.8 (-11.4, -2.1)	-4.9 (-9.7, -0.2)
Low	*Ref*	*Ref*
Emotional Social Support		
High	15.1 (10.7, 19.5)	14.9 (10.6, 19.3)
Medium	4.0 (-0.6, 8.5)	3.1 (-1.3, 7.6)
Low	*Ref*	*Ref*
Affectionate Social Support		
High	16.2 (11.8, 20.5)	15.2 (10.9, 19.5)
Medium	6.2 (1.7, 10.7)	5.2 (0.7, 9.6)
Low	*Ref*	*Ref*
Tangible Social Support		
High	17.3 (12.6, 21.9)	16.9 (12.3, 21.5)
Medium	5.4 (1.0, 9.7)	5.1 (0.7, 9.4)
Low	*Ref*	*Ref*
Social Interaction		
High	13.0 (-8.9, 17.1)	12.5 (8.4, 16.6)
Medium	-0.9 (-5.8, 3.9)	-1.0 (-5.8, 3.7)
Low	*Ref*	*Ref*
Overall Social Support		
High	15.6 (11.4, 19.8)	15.0 (10.8, 19.3)
Medium	4.6 (-0.1, 9.2)	3.5 (-1.0, 8.1)
Low	*Ref*	*Ref*

[a] Model 1: Unadjusted model

[b] Model 2: Adjusted for intervention, baseline viral load, age, race, ethnicity, and education

*Positive urinalysis for methamphetamine, amphetamine, cocaine, or opioid

D. MANUSCRIPT 3: FACILITATORS AND BARRIERS TO ENGAGMENT IN HIV CARE IN THE SOUTHERN NATIONS, NATIONALITIES, AND PEOPLE'S REGION OF ETHIOPIA

D.1. Introduction

Nearly 37.7 million people are living with HIV world-wide, of which eastern and southern Africa carry a large burden.[37,127] Global 95-95-95 goals to reach a 2030 target of ending AIDS indicate that 95% of all persons living with HIV (PLWH) will know their status; 95% of those diagnosed will have sustained access to antiretroviral therapy (ART); and 95% of those who have received ART will be virally suppressed.[40,128] Despite making process in reducing HIV infections by 70% between 2010 and 2022, current estimates indicate that there are 610,000 Ethiopians living with HIV in 2022.[41] Of those PLWH in Ethiopia, approximately 85% know their status, 82% are on ART, and 80% have suppressed viral loads (Figure 4).[41,42] Retention in HIV care among PLWH is necessary in order to achieve the 95-95-95 goals for 2030 as HIV care appointments are crucial for receiving prescriptions for ART and maintaining viral suppression. However, a 2020 systematic review and meta-analysis found that approximately 70% of Ethiopians living with HIV were considered retained in care.[129] Identifying the remaining 30% and understanding the barriers and facilitators to being retained in care will be important to achieve the 95-95-95 goals for 2030.

Retention in care may be more challenging in rural areas. More than three-quarters of the population of Ethiopia live in rural settings, including the Southern Nations, Nationalities, and People's Region (SNNPR), and the HIV epidemic in rural

settings differs from that in urban areas.[130-132] Living in a rural compared to an urban area has shown to be a barrier to both retention in care and continual use of ART and persons living in rural areas were less likely to be retained in HIV care compared to those living in urban areas.[129,133,134] It is important to understand the unique individual, social, and structural facilitators and barriers to retention in care among PLWH in rural Ethiopia in order to reach the 95-95-95 goals by 2030.[40,128]

Additional barriers to retention in care and discontinuing ART include being single,[129,133] alcohol or tobacco use,[133] physical or mental health illness,[133,135,136] HIV-related stigma,[135,137] and non-adherence to ART,[129] while HIV status disclosure,[129,133,138] and social support[135,138] have been shown to facilitate retention in care. Specifically, focus groups conducted by members of this research team suggested multiple barriers to retention in care among men and women living with HIV in rural Ethiopia, including patient-related (misconceptions about HIV and ART and drug use), clinic-related (negative experiences receiving HIV care including staff attitude, change in treatment plans, overcrowding), medication-related (side effects), socially-related (stigma and social support), as well as structural-related (transportation, cost) barriers.[139] Additional research from Ethiopia suggests stigma is a barrier to retention in care and rural residents in Ethiopia were found to have higher rates of prejudice and stigmatizing attitudes towards PLWH compared to urban areas.[137,140,141]

This analysis expands upon both the qualitative focus groups[139] and randomized trial[142,143] conducted by the study team to identify additional factors associated with retention in care and to describe the quantitative association of individual, social, and

structural-level facilitators and barriers to retention in HIV care among persons who are initiating HIV treatment specifically in the rural SNNPR of Ethiopia.

D.2. Methods

A detailed description about the SHAMA study and its primary results has been previously published.[142,143]

D.2.1 Procedures and Participants

The current study is a secondary analysis of the SHAMA study, a 36-month cluster randomized trial of a community health worker (CHW) intervention to promote retention in HIV care among persons entering HIV care in the rural SNNPR of Ethiopia.[142,143] Among the 16 largest district hospitals and 16 largest health centers, eight were randomly allocated to the CHW intervention and eight to the control arm. [142,143] Participants were enrolled between October 2015 and April 2017.[142,143] Those randomized to hospitals and health centers in the intervention arm were assigned a CHW who provided psychosocial and emotional benefits, including health education, counseling, and social support.[142,143] Those randomized to the control arm received the standard of care for HIV treatment in Ethiopia.[144] Overall, the SHAMA study found no difference in retention in care by treatment arm.[142,143]

D.2.2 Measures.

In addition to a clinical record review, participants completed a health survey at baseline and months 12, 24, and 36. Annual interviews were administered verbally by project officers at the hospital or clinic sites.[142,143]

Demographics. Demographic information was collected at baseline. Data included age in years (categorized as 16 – 25; 26 – 44; 45 – 80), gender (male, female), and current marital status (single, married, widowed/divorced/separated, or other). Education was categorized as the highest level of education received including no school, some primary school (grades 1 – 7), completed primary school (grade 8), completed grades 9 – 11, completed secondary school (grade 12), and higher education (beyond secondary school). Clinical records were used to abstract World Health Organization (WHO) Stage (Stage 1: asymptomatic to Stage 4: severely symptomatic),[145] CD4 count ($\leq$ 200 cells / mm^3, 200 – $\leq$350 cells / mm^3, >350 cells / mm^3) and number of months between enrollment and HIV diagnosis (0 – 2 months, 3 – 12 months, and more than 12 months).

Individual-Level Barriers to Care. Individual-level barriers to care were collected at baseline. This included HIV knowledge, the ability to carry out normal activities, number of chronic health conditions, and depressive symptoms. HIV knowledge was measured using eight statements with "agree" or "disagree" response options assessing study participants HIV knowledge, HIV treatment, and HIV care. The total number of correct responses was summed and categorized as low HIV knowledge (0 – 5 correct) and high HIV knowledge (6 – 8 correct). State of health was assessed using six

classifications adapted from the Karnofsky Performance Status Scale to describe their ability to carry out normal activities and care for personal needs.[146] Current state of health was dichotomized as those being able to carry out normal activities and care for personal needs and those unable to care for personal needs or carry out normal activities. Participants were additionally asked to report if they were experiencing recent health problems that have lasted for more than one month, including diarrhea, fevers, cough, pain, fatigue or tiredness, and weight loss. Participants were classified as having any chronic symptoms or none. Depressive symptoms in the previous week was assessed using the 10-item Center for Epidemiologic Studies Depression Scale.[78] Participants were classified as having depressive symptoms (Score: 10+) or no depressive symptoms (Score: 0 – 9).[78]

Social-Level Barriers to Care. Social-level barriers to care were collected at baseline. Data collected included social support, HIV-related stigma, and HIV-disclosure. Two subscales of the Medication Outcomes Survey was used to assess emotional (8 items) and tangible social support (4 items) using a 4-point Likert scale.[84] The sum of responses for each subscale were calculated and participants were classified based on quartiles as having low (0 – 25th percentile), medium, (25th to 75th percentile) or high (75th to 100th percentile) values of social support. An overall social support measure was calculated as the sum of emotional and tangible social support and classified into low (0 – 25th percentile), medium, (25th to 75th percentile) or high (75th to 100th percentile) levels of overall social support. HIV-related stigma in the past 3 months was assessed using components of the HIV/AIDS Stigma Instrument, including negative self-

perception (5-items) and social isolation (5-items).[147] Negative self-perception was split into three categories (No indication of negative self-perception (score: 0), low negative self-perception (score: > 0 – < 1) or high negative self-perception (score: 1 – 3). Social isolation was dichotomized into those indicating no social isolation (score: 0) or those with some level of social isolation (> 0 – 3). Lastly, participants were asked to report on their HIV disclosure to (1) family members and (2) friends or community members. Disclosure to immediate family members was defined as at least one disclosure to either the study participant's mother, father, partner, children, or other relatives (brother, sister, aunt, uncle, etc). Disclosure to friends or community members was defined as at least one disclosure to friends or other community members.

Structural Level Barriers to Care. Participants were asked about their typical experience while traveling to their HIV clinic or care provider. Time from a participant's home to the HIV clinic was collected (< 1 hour and 1 hour or more), as well as their typical mode of transportation (walking, bus/car, other).

D.2.3 Gap in HIV Care.

During follow-up, individuals were classified as having died, transferred to another HIV clinic, and/or had a gap in clinical care during the 36-month follow-up. Current Ethiopian guidelines recommend monthly visits to their HIV care provider and gap in clinic care was defined as greater than 120 days from their last known clinical or drug pick up appointment with no subsequent appointments, which represents individuals being more than 90 days past their next scheduled appointment.[142-144,148] Some

participants received 6 months of ART and were not recommended for monthly visits and received a slightly different definition for gap in clinical care. For these individuals, a gap in care was defined as more than 270 days from their last known clinical or drug pick up appointment with no subsequent appointments, which represents being more than three-months past the end of their 6-month prescription. Individuals who transferred or died prior to a gap in care were censored from analysis.

D.2.4 Statistical Analysis.

Risk differences (RDs) were calculated using generalized linear models with a binomial family and identity link clustering for hospital to evaluate the association of the individual, social, and structural facilitators and barriers on gap in care. Two models were fit for each of the 13 exposures of interest (4 individual-level, 7 social-level, 2 and structural-level) with gap in care at 12 months and 36 months. The first model adjusted for whether the participant attended a clinic in the intervention or control arm. The second model was fit to estimate adjusted risk differences, adjusting for baseline demographics and clinical characteristics (age, gender, marital status, education, and WHO HIV clinical stage) as well as the whether the person attended a clinic in the intervention or control arm. To account for clustering of the participants within the 32 clinic sites, cluster-robust standard errors were used. Inverse-probability weights were used to account for censoring of individuals who transferred to another clinic or died prior to a gap in care.[149,150] These weights were generated conditional on age, gender, marital status, time since initial diagnosis of HIV infection, and WHO HIV clinical stage.

Subsequent sensitivity analyses among the control group were run for both models at the 12-month and 36-month outcomes (Results in Appendix). All analyses were conducted using STATA 14.

D.3. Results

D.3.1 Demographics.

Demographic characteristics of the 1,799 participants are summarized in Table 12. The majority of participants were female (59%) and between the ages of 26 and 44 (62%) with a mean age of 33 years. Only one-quarter of participants completed secondary school or higher, with the same proportion having no school; approximately half had completed primary school. Nearly half of all participants were married, followed by those who were widowed, divorced, or separated (35%). Fifteen percent of participants were single.

D.3.2 HIV-Related Characteristics.

At baseline, nearly two-thirds of participants had been diagnosed with HIV within 2 months; 16% had been diagnosed for more than one year (Table 12). Of those with available CD4 counts (21% of participants are missing CD4 counts at baseline), equal proportions of the study population had CD4 counts < 200 (39%) and > 350 (37%). Forty percent of participants were considered WHO HIV Stage 3 or 4.

D.3.3 Gap in Care.

Overall, 507 participants (28.2%) experienced a gap in care during the first 12-months, 1,070 (59.5%) did not experience a gap in care, and 222 (12.3%) were censored. By the end of the study (36-months), 428 had not experienced a gap in care (24%), 1,090 (60.6%) experienced a gap in care, while 281 (15.6%) participants were censored (data not shown). Additional information about the censored participants can be found in the Appendix.

D.3.4 Individual-Level Barriers and Facilitators.

At baseline, approximately 60% of participants had a high level of HIV knowledge (Table 13) and more than 80% could carry out normal activities. Nearly 85% of participants had at least one chronic condition (diarrhea, fevers, cough, pain, fatigue or tiredness, or weight loss), with more than half of participants experiencing fatigue or tiredness (66.4%) and weight loss (67.1%). More than half of participants experienced depressive symptoms (55.1%). At 12-months, individuals with lower HIV knowledge were more likely to experience a gap in care compared to those with higher HIV knowledge (RD = 5.0; 95% CI: 0.2, 9.7) after adjusting for baseline demographics and clinical characteristics. Individuals who were unable to carry out normal activities were more likely to experience a gap in care compared to those who were able to (RD = 4.0; 95% CI: -1.3, 9.3) in adjusted models. However, none of these associations were evident at month-36. Having chronic conditions and depressive symptoms were not associated with experiencing a gap in care.

D.3.5 Social-Level Barriers and Facilitators.

Approximately one-quarter of individuals had high emotional (27.8%) and tangible (23.1%) social support (Table 14). More than one-third of participants experienced high levels of negative self-perception (34.4%) while 220 (12.2%) indicated they had experienced social isolation. Most participants (71.4%) in this study disclosed their HIV status to at least one family member, while less than one-quarter (21.6%) disclosed their status to friends or community members (21.6%) Individuals who did not disclose their HIV status to family members were more likely to experience a gap in care within 12 months (RD = 11.7; 95% CI: 6.1, 17.3) and 36-months (RD = 9.3; 95% CI: 2.4, 16.3). Disclosure to friends and/or community members was not associated with a gap in care within 12 or 36 months. Overall, individuals with low or medium levels of social support were more likely to experience a gap in care compared to those with high levels within 12-months, but these differences are most profound at 36 months. Individuals with low (RD = 9.5; 95% CI: 2.6, 16.4) and medium levels of social support (RD = 6.2; 95% CI: -1.8, 14.3) were more likely to experience a gap in care compared to individuals with high levels of social support at 36 months. Within 12-months, individuals with low levels of negative self-perception HIV stigma were less likely to experience a gap in care compared to those with no negative self-perception HIV stigma (RD = -6.4; 95% CI: -12.4, -0.4), but there were no differences evident between those with high levels of negative self-perception HIV stigma compared to those with none. However, no differences by level of negative self-perception were evident at month-36.

Individuals with higher levels of social isolation had higher risk of experiencing at gap in care within 12-months (RD = 5.1; 95% CI: -3.86, 13.9), but not at 36-months.

D.3.6 Structural-Level HIV Barriers.

The majority of participants had to travel less than one hour for their HIV care (59.9%) and travelled by bus or car (70.3%). Compared to those who travelled < 1 hour, individuals who traveled more than one hour were more likely to have a gap in care within 12-months (RD = 4.9; 95% CI: -1.3, 11.0). However, this was not evident at month-36. There were no differences due to mode of transportation on gap in care at the month-12 and month-36 assessments (Table 15).

D.4. Discussion

The aim of this study was to evaluate the association of individual, social, and structural-level barriers and facilitators on gap in care among PLWH initiating HIV treatment in Ethiopia. The findings of this study suggest that at the individual-level, having low HIV knowledge and being unable to carry out normal activities may be barriers to engagement with HIV care in the first year after initiating treatment, while at the social-level, disclosure to family members and improved social support may act as facilitators. At the structural-level, reducing the amount of time needed to travel to an HIV-clinic may reduce gaps in care.

At the individual-level, PLWH with low HIV knowledge are more likely to experience a gap in care within the first year of treatment compared to those with higher

HIV knowledge, but HIV knowledge was not found to impact long-term retention in care. Approximately 31% of those with low HIV knowledge experienced a gap in care within the first 12-months of treatment compared to 26% of those with higher HIV knowledge. However, at 36-months, the number of individuals with gaps in care increased to 62% among those with low HIV knowledge and 60% of those with high HIV knowledge. The results of this study suggest that increased HIV knowledge at HIV treatment initiation may improve engagement with HIV care within the first year of HIV care but may not in the long term. However, HIV knowledge did improve over the course of the 3-year study with more than 90% of participants having high HIV knowledge at the end of the study period. The results of this study are comparable with previous studies that have found that an association between HIV knowledge and engagement in care in qualitative interviews and focus groups.[137,139,151] The majority of participants were able to carry out normal activities (84%), and those who were unable to were more likely to experience a gap in care within 12-months, but not at 36-months. However, having chronic conditions other than HIV was not found to be associated with a gap in care in both the short (12 months) or long term (36 months). Although previous studies have shown an association between depression and gaps in care, our study found no association at both 12 and 36 months.[152,153] These results are similar to previous studies of depression and HIV engagement outcomes among PLWH in Malawi, South Africa, and Kenya, which found no difference in gap in care between those with and without depressive symptoms.[154-156] Rates of HIV-disclosure to immediate family members were similar between those with

and without depressive symptoms (70.4% vs 72.5%), which may explain why depression was not associated with gaps in care in this population.

In addition to individual-level factors, there are numerous social-level facilitators that were associated with retention in care both in the short-term (12-months) and long-term (36-months), in particular, disclosure and social support. Previous research by this study team has also shown than disclosure to any person as well as disclosure to a spouse or partner was associated with higher emotional and tangible support scores.[157] Disclosure to family members, including parents, spouses or partners, children, or other family members was associated with a decreased risk of gap in care in the short-term (12-months) as well as long-term (36-months). In the short-term, approximately 36% of those who did not disclose to family members had a gap in care compared to approximately one-quarter of those who had disclosed to family members. While most individuals experienced a gap in care in the long-term, those who disclosed to family members are less likely to experience a gap in care (58%) compared to those who did not disclose (67%). Disclosure of HIV status to family members has also been shown to be associated with increased adherence to antiretroviral therapy,[158-160] suppression of viral load,[159] and reduced levels of perceived stigma,[159] as well as clinical non-adherence or loss to follow-up.[161,162] Similar studies have also indicated that HIV disclosure may play a role in improving engagement with HIV care.[163,164] Rates of disclosure in our study among married or partnered individuals are similar to results from two systematic reviews that have shown that PLWH in Ethiopia have HIV disclosure rates to sexual partners around approximately 75%.[165,166] Improving rates of disclosure among PLWH

initiating treatment not only to sexual partners, but also other close family members, may be an important facilitator to improving both short-term and long-term retention in care. Compared to those who did not disclose, those who disclosed to family members were more likely to have high overall social support (32.0% vs 13.6%), high emotional support (33.0% vs 15.2%), and high tangible support (28.0% vs 11.1%).

Emotional and tangible social support can also be important facilitator in improving retention in care. Although having higher emotional or tangible social support was not found to be associated with retention in care in the short-term, having lower emotional and tangible support was found to be associated with increased risk of gaps in care in the long-term. Approximately one-quarter of participants in our study had medium to high levels of both emotional and tangible social support. Higher levels of emotional support may lead to reduced HIV-stigma and increased HIV knowledge while higher levels of tangible support indicate that the individual may have more help with daily chores or transportation to HIV clinics. The results of this study add to previous studies that have indicated increased social support has been known to increase retention in care among PLWH.[135,139,167]

Lastly, at the structural level, reducing the amount of time needed to travel to the HIV clinic may reduce gaps in care within 12-months, which is similar to previous studies that have shown that an increased distance to HIV clinic has been shown to be associated with retention in care,[168-170] whereas others have found that distance and time to HIV clinic has been shown to not be associated with retention in care.[171,172] One reason why PLWH may travel away from their homes to attend appointments is to avoid

stigma from their local community or HIV clinic staff.[172,173] Future studies should further evaluate the role stigma has on choosing the mode of transportation and time or distance travelled to an HIV clinic.

This study has several limitations. First, approximately 12% of our study population were censored due to transferring to another clinic or dying prior to a gap in care. Censored individuals were more likely to be WHO Category 3 or 4, have lower CD4 counts, diagnosed within 2 months, not able to carry out normal activities, have chronic illnesses, and travel more than one hour to an HIV clinical site. It is unknown if participants who were censored due to transferring to another HIV clinical site were retained in care at the new clinical site. Inverse-probability weighting was utilized as a method to mitigate this unknown.[149,150] Additionally, this study did not evaluate the role the HIV-clinic or medical provider may have on retention in care.

Overall, this study examined the association between numerous barriers and facilitators to retention in care among PLWH initiating treatment in Ethiopia that could be used to increase the relevance of interventions in future studies. At the individual level, increasing HIV knowledge may reduce gaps in care, specifically in the first year of treatment. Similarly, interventions aimed at improving overall social support, including both tangible and emotional support, as well as increasing disclosure to family members may be beneficial in reducing gaps in care. Despite a small increase in gap in care among those who travelled further to attend HIV care appointments, improving transportation methods may provide better access to HIV treatment and may improve engagement with HIV care, which has been supported in previous studies.[174] Future studies should expand

upon this study to evaluate the role of individual, social, and structural barriers and facilitators to retention in care and sustained viral suppression.

Table 12. Demographics of SHAMA Participants

Baseline Demographics	Total (n = 1,799)	Gap in Care (n = 507)	No Gap in Care (n = 1,070)	Death / Transfer* (n = 222)
Age, mean (sd)	32.8 (9.2)	31.9 (9.1)	33.2 (9.2)	33.2 (8.9)
Age, %, (n)				
16 – 25	24.2 (435)	27.4 (139)	22.9 (245)	23.0 (51)
26 – 44	61.6 (1,108)	59.6 (302)	62.7 (671)	60.8 (135)
45+	12.3 (221)	11.0 (56)	12.5 (134)	14.0 (31)
Missing	1.9 (35)	2.0 (10)	1.9 (20)	2.2 (5)
Gender, %, (n)				
Male	40.7 (733)	41.2 (210)	39.3 (421)	45.9 (102)
Female	59.3 (1,066)	58.6 (297)	60.7 (649)	54.1 (120)
Current Marital Status, *%, (n)*				
Single	15.2 (274)	18.5 (94)	13.3 (142)	17.1 (38)
Married	49.4 (888)	46.5 (236)	51.8 (554)	44.1 (98)
Widowed / Divorced / Separated	35.1 (632)	34.7 (137)	34.7 (371)	38.3 (85)
Missing	0.3 (5)	0.2 (1)	0.3 (3)	0.5 (1)
Highest Level of Education Achieved, *%, (n)*				
No School	26.2 (471)	27.4 (139)	26.7 (286)	20.7 (46)
Primary School	47.4 (852)	47.3 (240)	46.5 (498)	51.4 (114)
Secondary School / Higher Education	26.4 (475)	25.2 (128)	26.6 (285)	27.9 (62)
Missing	0.1 (1)	0 (0)	0.1 (1)	0 (0)
WHO Stage, *%, (n)*				
Stage 1 / 2	58.8 (1,058)	57.8 (293)	62.3 (667)	44.1 (98)
Stage 3 /4	40.2 (723)	40.4 (205)	36.9 (395)	55.4 (123)
Missing	1.0 (18)	1.8 (9)	0.8 (8)	0.5 (1)
CD4 Count, *%, (n)*				
$\leq$ 200 cells/mm^3	30.9 (556)	23.7 (120)	31.5 (337)	44.6 (99)
200 - $\leq$ 350 cells/mm^3	18.6 (335)	15.4 (78)	20.9 (224)	14.9 (33)
> 350 cells/mm^3	29.5 (530)	35.3 (179)	29.2 (312)	17.6 (39)
Missing	21.0 (378)	25.6 (130)	18.4 (197)	23.0 (51)
Months since HIV diagnosis, *%, (n)*				
1 – 2 Months	64.3 (1,157)	68.6 (348)	59.8 (640)	76.1 (169)
3 – 12 Months	17.4 (313)	16.8 (85)	19.3 (207)	9.5 (21)
> 12 Months	15.8 (285)	12.6 (64)	18.3 (196)	11.3 (25)
Missing	2.5 (44)	2.0 (10)	2.5 (27)	3.1 (7)

* Death or transfer before a gap in care

Table 13. Individual-Level Barriers and Facilitators on Gap in Care

Individual Level-Barriers	Total Population (n = 1,799)	Month – 12			Month - 36		
		Gap in Care n (%)	Risk Difference (95% CI)[1]	Risk Difference (95% CI)[2]	Gap in Care n (%)	Risk Difference (95% CI)[1]	Risk Difference (95% CI)[2]
HIV Knowledge Category, *% (n)*							
Low HIV Knowledge	39.4 (709)	31.0 (220)	5.2 (0.8, 9.6)	5.0 (0.2, 9.7)	61.5 (436)	1.0 (-5.8, 7.7)	0.4 (-6.8, 7.5)
High HIV Knowledge	60.6 (1090)	26.3 (287)	Ref	Ref	60.0 (654)	Ref	Ref
Carry out normal activities, *% (n)*							
Can't carry out normal activities	15.7 (282)	27.7 (78)	5.2 (0.1, 10.2)	4.0 (-1.3, 9.3)	54.6 (154)	2.2 (-6.3, 10.7)	1.5 (-6.0, 9.1)
Can carry out normal activities	84.1 (1,513)	28.3 (428)	Ref	Ref	61.6 (932)	Ref	Ref
Chronic Conditions, *% (n)*							
Chronic conditions	84.0 (1,511)	27.5 (416)	-1.5 (-7.9, 4.9)	-2.9 (-9.4, 3.7)	59.5 (899)	0.8 (-9.2, 10.8)	0.7 (-9.0, 10.5)
No chronic conditions	16.0 (288)	31.6 (91)	Ref	Ref	66.3 (191)	Ref	Ref
Depressive Symptoms, *% (n)*							
Depressive Symptoms	55.1 (991)	27.5 (273)	0.5 (-5.1, 6.0)	0.2 (-5.2, 5.7)	59.2 (587)	-1.1 (-8.0, 5.8)	-1.3 (-7.6, 5.0)
No Depressive Symptoms	44.9 (807)	28.9 (233)	Ref	Ref	62.2 (502)	Ref	Ref

[1] Model 1: Adjusting for randomization

[2] Model 2: Adjusting for randomization, demographics (age, gender, marital status, education, and WHO HIV clinical stage)

Table 14. Social-Level Barriers and Facilitators on Gap in Care

Social-Level Barriers	Total Population (n = 1,799)	Month-12			Month-36		
		Gap in Care n (%)	Risk Difference[1] (95% CI)	Risk Difference[2] (95% CI)	Gap in Care n (%)	Risk Difference[1] (95% CI)	Risk Difference[2] (95% CI)
Emotional Social Support, *n (%)*							
Low Emotional Support	458 (25.5)	137 (29.9)	5.8 (-0.8, 12.4)	4.4 (-2.5, 11.3)	299 (65.3)	12.1 (5.3, 19.0)	9.9 (2.9, 16.9)
Medium Emotional Support	835 (46.4)	235 (28.1)	3.9 (-2.5, 10.3)	3.4 (-3.2, 9.9)	507 (60.7)	9.1 (1.8, 16.4)	6.9 (-0.2, 14.0)
High Emotional Support	500 (27.8)	132 (26.4)	Ref	Ref	279 (55.8)	Ref	Ref
Tangible Social Support, *n (%)*							
Low Tangible Support	417 (23.2)	124 (29.7)	6.9 (-2.3, 16.2)	5.3 (-4.7, 15.3)	268 (64.3)	11.5 (1.0, 22.0)	8.3 (-1.6, 18.2)
Medium Tangible Support	965 (53.6)	278 (28.8)	4.9 (-2.1, 11.8)	4.4 (-2.5, 11.3)	589 (61.0)	6.5 (-3.1, 16.0)	5.3 (-3.6, 14.2)
High Tangible Support	415 (23.1)	104 (25.1)	Ref	Ref	232 (55.9)	Ref	Ref
Overall Social Support, *n (%)*							
Low Social Support	473 (26.3)	138 (29.2)	5.8 (-1.6, 13.2)	4.4 (-3.2, 11.9)	307 (64.9)	12.3 (5.6, 19.0)	9.5 (2.6, 16.4)
Medium Social Support	840 (46.7)	241 (28.7)	5.1 (-2.1, 12.2)	4.6 (-2.4, 11.5)	509 (60.6)	8.0 (-0.8, 16.7)	6.2 (-1.8, 14.3)
High Social Support	479 (26.6)	125 (26.1)	Ref	Ref	269 (56.2)	Ref	Ref
Negative Self-Perception, *n (%)*							
High HIV Stigma	619 (34.4)	175 (28.3)	-2.0 (-7.5, 3.6)	-2.1 (-7.8, 3.6)	368 (59.5)	0.4 (-7.9, 8.7)	-0.4 (-7.1, 6.3)
Low HIV Stigma	714 (39.7)	183 (25.6)	-5.9 (-11.8, 0.1)	-6.4 (-12.4, -0.4)	432 (60.5)	1.9 (-11.1, 14.8)	0.9 (-11.1, 12.9)
None	458 (25.5)	148 (32.3)	Ref	Ref	284 (62.0)	Ref	Ref
Social Isolation, *n (%)*							
HIV Stigma	220 (12.2)	68 (30.9)	5.3 (-3.2, 13.7)	5.1 (-3.6, 13.9)	131 (59.6)	0.7 (-7.2, 8.7)	0.2 (-7.7, 8.1)
None	1,576 (87.6)	438 (27.8)	Ref	Ref	956 (60.7)	Ref	Ref
Disclosure (Family), *n (%)*							
No Disclosures	515 (28.6)	187 (36.3)	12.5 (7.2, 17.7)	11.7 (6.1, 17.3)	345 (67.0)	10.2 (3.6, 16.8)	9.3 (2.4, 16.3)
At least one disclosure	1,284 (71.4)	320 (24.9)	Ref	Ref	745 (58.0)	Ref	Ref
Disclosure (Community), *n (%)*							
No Disclosures	1,410 (78.4)	401 (28.4)	2.7 (-3.1, 8.5)	3.7 (-2.1, 9.4)	847 (60.1)	-0.6 (-7.3, 6.1)	1.2 (-4.3, 6.6)
At least one disclosure	389 (21.6)	106 (27.2)	Ref	Ref	243 (62.5)	Ref	Ref

[1] Model 1: Adjusting for randomization

[2] Model 2: Adjusting for randomization, demographics (age, gender, marital status, education, and WHO HIV clinical stage)

Table 15. Structural Barriers and Facilitators on Gap in Care

	Total Population (n = 1,799)	Month-12			Month-36		
		Gap in Care n (%)	Risk Difference (95% CI)[1]	Risk Difference (95% CI)[2]	Gap in Care n (%)	Risk Difference (95% CI)[1]	Risk Difference (95% CI)[2]
Time to HIV Clinic, n (%)							
1 + hours	722 (40.1)	211 (29.2)	4.1 (-2.2, 10.4)	4.9 (-1.3, 11.0)	429 (59.4)	-0.2 (-6.1, 5.7)	0.9 (-4.8, 6.6)
< 1 hour	1,077 (59.9)	296 (27.5)	Ref	Ref	661 (61.4)	Ref	Ref
Mode of Transportation, n (%)							
Walking	442 (24.6)	125 (28.3)	-1.8 (-10.6, 6.9)	-2.0 (-10.3, 6.4)	281 (63.6)	-0.4 (-11.3, 10.6)	-0.4 (-9.1, 8.4)
Bus, Car	1,265 (70.3)	357 (28.2)	-3.0 (-11.3, 5.4)	-2.6 (-10.6, 5.4)	753 (59.5)	-4.8 (-13.0, 3.3)	-3.3 (-11.1, 4.5)
Other	89 (5.0)	24 (27.0)	Ref	Ref	55 (61.8)	Ref	Ref

[1] Model 1: Adjusting for randomization

[2] Model 2: Adjusting for randomization, demographics (age, gender, marital status, education, and WHO HIV clinical stage)

E. SUMMARY OF FINDINGS

This dissertation aimed to evaluate and identify potential facilitators and barriers to achieving thresholds along the HIV Continuum of Care, in particular viral suppression and retention in HIV care. Manuscript 1 and Manuscript 2 utilized data from a randomized control trial, *Thrive with Me,* to examine first, the relationship between user engagement and viral suppression, and second, the relationship between individual and social-level factors and patient activation, among a sample of MSM with low self-reported adherence or history of detectable viral loads. Data for manuscript 3 were collected from a cluster randomized trial of a community health worker intervention aimed at improving retention in HIV care among persons initiating HIV care in Ethiopia and evaluated the association between individual, social, and structural-level facilitators and barriers to retention in care.

Manuscript 1 aimed to describe user engagement with *Thrive with Me,* an mHealth intervention among study participants and evaluate the association between overall engagement with *TWM* and individual component engagement (asynchronous peer exchanges, HIV-related information, and self-monitoring of ART adherence) and subsequent viral suppression. Although only 55% of those who received the *TWM* intervention actively engaged with the intervention, the majority of those who were users engaged with all of the individual *TWM* components at least once. Additionally, individuals who had high overall engagement with the *TWM* intervention and those who were highly engaged with two or more of the *TWM* components were more likely to be virally suppressed at the end of the active intervention period. High proportions of

individuals who were engaged with the asynchronous peer exchanges achieved viral suppression not only following the active intervention, but also during longitudinal follow-up. However, engagement with HIV-related information and self-monitoring of ART was not associated with viral suppression. This study is one of the first conducted to evaluate the role of the individual behavioral intervention components of an mHealth intervention on viral suppression among MSM living with HIV.

Manuscript 2 evaluated the association between individual-level and social-level factors and patient activation in a community-sample of MSM living with HIV participating in an mHealth intervention. Overall, we found that although consistent with populations of individuals with other chronic conditions, patient activation among this population was higher than previously established estimates of patient activation in the general population. More than half of participants were considered to have the highest level of patient activation. Numerous individual-level and social-level factors were associated with increased patient activation. At the individual level, Information, Motivation, and Behavioral Skills and marijuana use were positively associated with patient activation, while drug and alcohol use, depression, life chaos, and perceived stress were inversely associated with patient activation. At the social-level, social support was positively associated with patient activation while HIV-related stigma was inversely associated with patient activation. This study is the first to our knowledge to evaluate the association of individual-level and social-level factors in patient activation among MSM living with HIV as well as the first to evaluate use of five illicit drugs as confirmed by urinalysis among PLWH.

In Manuscript 3, we evaluate the association of individual-level, social-level, and structural-level factors and short and long-term retention in care among individuals initiating HIV-care in the Southern Nations, Nationalities and Peoples Region of Ethiopia. After initiating HIV-care, approximately one-quarter of participants experienced a gap in care within one-year of initiating HIV treatment while more than half of participants had experienced a gap in care within three-years. Within one year, individuals with lower HIV knowledge and the inability to carry out normal activities were most likely to experience a gap in care at one-year. Disclosure to family and social support were found to be important as individuals who disclosed to family members and those with higher levels of social support were less likely to experience a gap in care within one-year and three-years. Lastly, transportation may be a barrier to being retained in care as individuals who traveled further to receive HIV care were more likely to have a gap in care.

The results of the manuscripts presented in this dissertation help to identify potential areas of intervention to improve viral suppression and engagement with HIV care among PLWH both in the United States and in Ethiopia. Key findings for all three manuscripts included social support. In Manuscript 1, asynchronous peer exchanges, were found to be associated with viral suppression throughout the 17-month study. Approximately half of the asynchronous peer exchanges during the active intervention had a theme of social support. Within the asynchronous peer exchanges, participants were actively seeking emotional support and providing informational support. In Manuscript 2, we found that individuals with higher levels of social support have higher

levels of patient activation, indicating that social support may impact an individual's ability and the behavioral skills necessary to engage with their health care and decision making. Lastly, in Manuscript 3, individuals who disclosed their HIV status to family members had higher levels of social support, and both emotional and tangible social support and disclosure were associated with being retained in care in the short-term and long- term after initiating HIV care. Increasing social support among persons living with HIV may be an important facilitator to improving HIV-related outcomes, including those on the HIV Continuum of Care.

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APPENDIX

Appendix 1. Censored Participants in the SHAMA Study

A total of 222 participants transferred or died (censored) prior to a potential gap in care date within the first 12 months. Of those who were censored, 35% died (n = 78) and 65% (n = 144) transferred. Individuals who were considered WHO Category 3 or 4 were more likely to be censored compared to those who were considered WHO Category 1 or 2 (17% vs 9%). Eighty percent of those who died and 42% of those who transferred were WHO Category 3 or 4. Those with lower CD4 counts ($\leq$ 200 cells/mm^3) were more likely to be censored compared to those with > 350 cells/mm^3 (17.8% vs 7.4%). Sixty-percent of those who died and 36% of those who transferred had CD4 counts $\leq$ 200 cells/mm^3.

Those who were diagnosed with HIV in the previous 2 months were more likely to be censored (14.6%) compared to those who were diagnosed between 3 months and 1 year (6.7%) and more than one year (8.9%). Seventy-three percent of those who died and 78% of those who transferred had been diagnosed in the previous two months. Additionally, those who were not able to carry out normal activities were more likely to be censored compared to those who were able to carry out normal activities (22.3% vs 10.5%) and those with chronic illnesses (13.5%) were more likely to be censored compared to those without chronic conditions (6.3%). Forty-five percent of those who died and 19% of those who transferred were not able to carry out normal activities while 100% of those who died and 88% of those who transferred had chronic conditions. Similarly, individuals who traveled more than one hour to the clinic were more likely to

be censored than those who traveled less than one hour (14.4% vs 11.0%). Forty-six percent of those who died and 47% of those who transferred travelled more than 1 hour to their clinic. There were no differences in demographic or social-level barriers between censored individuals and those who remained in the study.

Appendix Tables 1 – 3. Individual, Social, and Structural-Level Barriers and Facilitators on Gap in Care among Control Participants

Table 16. [Appendix Table 1] Individual-Level Barriers and Facilitators on Gap in Care (Control Participants)

Individual Level-Barriers	Control Group (n = 980)	Month – 12			Month - 36		
		Gap in Care n (%)	Risk Difference (95% CI)[1]	Risk Difference (95% CI)[2]	Gap in Care n (%)	Risk Difference (95% CI)[1]	Risk Difference (95% CI)[2]
HIV Knowledge Category, *n (%)*							
Low HIV Knowledge	380 (38.8)	132 (34.7)	7.6 (2.9, 12.2)	7.1 (1.7, 12.5)	246 (64.7)	1.4 (-7.5, 10.3)	0.7 (-8.8, 10.3)
High HIV Knowledge	600 (61.2)	164 (27.3)	Ref	Ref	375 (62.5)	Ref	Ref
Carry out normal activities, *n (%)*							
Can't carry out normal activities	139 (14.2)	42 (30.2)	5.9 (-2.7, 14.5)	3.6 (-5.6, 12.9)	83 (59.7)	6.7 (-5.3, 18.6)	5.0 (-6.8, 16.9)
Can carry out normal activities	839 (85.6)	254 (30.3)	Ref	Ref	536 (63.9)	Ref	Ref
Chronic Conditions, *n (%)*							
Chronic conditions	825 (84.2)	247 (29.9)	0.3 (-7.9, 8.6)	-1.8 (-10.4, 6.7)	522 (63.3)	6.5 (-4.6, 17.6)	6.4 (-4.9, 17.7)
No chronic conditions	155 (15.8)	49 (31.6)	Ref	Ref	99 (63.9)	Ref	Ref
Depressive Symptoms, *n (%)*							
Depressive Symptoms	507 (51.7)	148 (29.2)	-1.1 (-6.3, 4.1)	-1.9 (-7.7, 3.9)	310 (61.1)	-3.3 (-13.4, 6.9)	0.7 (-6.6, 7.9)
No Depressive Symptoms	473 (48.3)	148 (31.3)	Ref	Ref	311 (65.8)	Ref	Ref

[1] Model 1: Adjusting for randomization

[2] Model 2: Adjusting for randomization, age, gender, marital status, education, and WHO HIV clinical stage

Table 17. [Appendix Table 2] Social Level Barriers and Facilitators on Gap in Care (Control Participants)

Social-Level Barriers	Control Group (n = 980)	Month – 12			Month - 36		
		Gap in Care n (%)	Risk Difference (95% CI)[1]	Risk Difference[2] (95% CI)	Gap in Care n (%)	Risk Difference (95% CI)[1]	Risk Difference[2] (95% CI)
Emotional Social Support, *n (%)*							
Low Emotional Support	235 (24.0)	73 (31.1)	5.7 (-3.2, 14.6)	2.0 (-7.8, 11.8)	157 (66.8)	13.2 (4.8, 21.5)	10.3 (-0.1, 20.6)
Medium Emotional Support	426 (43.5)	134 (31.5)	5.2 (-2.8, 13.2)	3.8 (-5.2, 12.8)	283 (66.4)	12.1 (3.8, 20.5)	9.6 (1.1, 18.0)
High Emotional Support	317 (32.3)	88 (27.8)	Ref	Ref	179 (56.5)	Ref	Ref
Tangible Social Support, *n (%)*							
Low Tangible Support	240 (24.5)	75 (31.3)	5.6 (-9.1, 20.4)	1.6 (-14.3, 17.5)	157 (65.4)	10.8 (-4.4, 26.0)	6.8 (-7.4, 21.0)
Medium Tangible Support	500 (51.0)	156 (31.2)	4.0 (-7.2, 15.2)	1.8 (-9.2, 12.8)	329 (65.8)	8.9 (-4.1, 21.8)	6.8 (-4.5, 18.1)
High Tangible Support	240 (24.5)	65 (27.1)	Ref	Ref	135 (56.3)	Ref	Ref
Overall Social Support, *n (%)*							
Low Social Support	259 (26.4)	80 (30.9)	6.7 (-4.5, 17.9)	3.2 (-9.1, 15.4)	173 (66.8)	13.9 (5.7, 22.1)	11.0 (1.1, 20.8)
Medium Social Support	423 (43.2)	134 (31.7)	6.1 (-3.7, 15.8)	4.5 (-5.8, 14.8)	279 (66.0)	11.0 (0.1, 21.9)	8.8 (-0.8, 18.4)
High Social Support	296 (30.2)	81 (27.4)	Ref	Ref	167 (56.4)	Ref	Ref
Negative Self-Perception, *n (%)*							
High HIV Stigma	298 (30.4)	86 (28.9)	-2.5 (-10.3, 5.3)	-3.6 (-11.5, 4.4)	183 (61.4)	1.6 (-10.7, 13.8)	0.1 (-9.8, 9.8)
Low HIV Stigma	424 (43.3)	126 (29.7)	-3.6 (-11.6, 4.3)	-4.4 (-12.2, 3.4)	276 (65.1)	5.0 (-14.3, 24.4)	4.3 (-13.5, 22.1)
None	253 (25.8)	84 (33.2)	Ref	Ref	159 (62.8)	Ref	Ref
Social Isolation, *n (%)*							
HIV Stigma	100 (10.2)	31 (31.0)	3.2 (-7.8, 14.1)	2.3 (-8.8, 13.4)	61 (61.0)	-1.2 (-13.7, 11.2)	-2.4 (-13.8, 8.9)
None	879 (89.7)	265 (30.1)	Ref	Ref	559 (63.6)	Ref	Ref
Disclosure (Family), *n (%)*							
No Disclosures	305 (31.1)	121 (39.7)	14.3 (8.6, 20.0)	11.7 (5.0, 18.4)	214 (70.2)	9.2 (-0.4, 18.8)	8.0 (-2.2, 18.2)
At least one disclosure	675 (68.9)	175 (25.9)	Ref	Ref	407 (60.3)	Ref	Ref
Disclosure (Friends/Community), *n (%)*							
No Disclosures	770 (78.6)	232 (30.1)	2.7 (-4.2, 9.7)	5.5 (-1.6, 12.7)	475 (61.7)	-4.8 (-13.5, 3.8)	-2.1 (-7.8, 3.6)
At least one disclosure	210 (21.4)	64 (30.5)	Ref	Ref	146 (69.5)	Ref	Ref

[1] Model 1: Adjusting for randomization

[2] Model 2: Adjusting for randomization, demographics (age, gender, marital status, education, and WHO HIV clinical stage

Table 18. [Appendix Table 3] Structural-Level Barriers and Facilitators on Gap in Care (Control Participants)

Social-Level Barriers	Control Group (n = 980)	Month – 12			Month - 36		
		Gap in Care n (%)	Risk Difference (95% CI)[1]	Risk Difference (95% CI)[2]	Gap in Care n (%)	Gap in Care n (%)	Risk Difference (95% CI)[1]
Time to HIV Clinic, n (%)							
1 + hours	394 (40.2)	123 (31.2)	6.1 (-1.2, 13.5)	7.8 (1.9, 13.7)	230 (58.4)	-5.6 (-13.0, 1.8)	-3.8 (-11.0, 3.4)
< 1 hour	586 (59.8)	173 (29.5)	Ref	Ref	391 (66.7)	Ref	Ref
Mode of Transportation, n (%)							
Walking	225 (23.0)	64 (28.4)	-8.4 (-25.3, 8.5)	-8.7 (-25.3, 7.9)	150 (66.7)	7.6 (-15.4, 30.7)	3.9 (-19.5, 27.3)
Bus, Car	726 (74.1)	221 (30.4)	-7.8 (-24.6, 8.9)	-6.2 (-21.8, 9.3)	453 (62.4)	1.6 (-17.1, 20.3)	1.7 (-18.7, 22.2)
Other	28 (2.9)	10 (35.7)	Ref	Ref	17 (60.7)	Ref	Ref

[1] Model 1: Adjusting for randomization

[2] Model 2: Adjusting for randomization, demographics (age, gender, marital status, education, and WHO HIV clinical stage