Thesis

Longitudinal assessment of psychosocial outcomes for patients enrolled in multidisciplinary HIV care with rapid and cost-covered treatment

submitted by

Lea Julia Bischof

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Univ.-Prof. Dr. med. univ. Andrea Siebenhofer-Kroitzsch
Assoc. Prof., MD, PhD Bertrand Lebouché

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Declaration of Academic Integrity

I hereby confirm that the present diploma thesis is the result of my own independent scholarly work. I also confirm that in all cases, where material from the work of others (in books, articles, essays, dissertations, and on the internet) is acknowledged, quotations and paraphrases are clearly indicated. No material other than that cited in the reference list has been used. I have read and understood the Medical University's regulations and procedures concerning plagiarism.

Graz, 21.12.2023 *Lea Julia Bischof m.p.*

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Zusammenfassung

Kontext: Psychosoziale Herausforderungen (z.B., psychiatrische Komorbiditäten) stellen beträchtliche Barrieren in der Behandlung von Menschen mit HIV (MMH) dar. Multidisziplinäre Versorgungsmodelle mit Ressourcen zur Unterstützung der psychischen Gesundheit, sowie kostenfreier und schnell verfügbarer antiretroviraler Therapie (ART), können Patienten mit psychosozialen Problemen potenziell entlasten. Bisher gibt es wenig Daten, die die mentale Gesundheit und assoziierte Faktoren bei MMH in einem solchen Versorgungsmodell untersuchen.

Zielsetzung: Beurteilung von psychischer Belastung, wahrgenommener HIV-bezogene Stigmatisierung und wahrgenommener sozialer Unterstützung von MMH in einem multidisziplinären Versorgungsmodell mit kostenfreier, zeitnaher ART-Initiierung.

Studiendesign: 96-wöchige prospektive mixed-methods Kohortenstudie in einem quartären HIV-Versorgungszentrum. Das Team beinhaltete folgende Berufsgruppen: Arzt*Ärztin, Gesundheitskrankenpfleger*in, Sozialarbeiter*in, klinische*r Pharmazeut*in, Psychiater*in. Die ART wurde den Patient*innen vor Ort kostenlos und so früh wie möglich (idealerweise innerhalb von 7 Tagen) nach Anbindung an das Zentrum zur Verfügung gestellt.

Studienpopulation: Neu-diagnostizierte MMH rekrutiert ab Januar 2020. Mit Juni 2022, bestand die Studienpopulation aus 39 Teilnehmern. Die Mehrheit war männlich (n=32, 82%), mit Migrationshintergrund (n=30, 77%), arbeitslos (n=23, 59%), und hatte zumindest einen Hochschulabschluss (n=25, 64%).

Materialien und Methoden: Folgende Patient Reported Outcome Measures (PROMs) wurden in Woche 4, 24, 48, und 96 ausgewertet: (1) Kessler Psychological Distress Scale 6-item version (Skala von 6-30; Werte zwischen 19-30 deuten auf ernste psychische Belastung hin); (2) Internalized AIDS-Related Stigma Scale (Skala von 0-7; höhere Werte deuten auf mehr wahrgenommene Stigmatisierung hin); und (3) Medical Outcomes Study Social Support Survey (Skala von 0-100; höhere Werte deuten auf mehr wahrgenommene soziale Unterstützung hin). Deskriptive statistische Parameter sowie Ergebnisse der Linear-mixed-model Analyse werden angeführt.

Ergebnisse: Über die vier Zeitpunkte hinweg reichten Durchschnittswerte für psychische Belastung von 22.0-25.6 (SD: 4.0-6.8), für Stigma von 3.9-5.2 (SD: 2.1-2.3), sowie von 48.8-59.7 (SD: 28.7-36.0) für wahrgenommene soziale Unterstützung. Bei allen PROMs, wurde kein signifikanter Unterschied der Ergebnisse hinsichtlich Veränderung im Verlauf und soziodemographischen Hintergrund bei Studieneinschluss gefunden.

Schlussfolgerung: Vorläufige Ergebnisse zeigen, dass MMH unabhängig ihres soziodemographischen Hintergrundes, weiterhin Herausforderungen im Bereich mentale Gesundheit, Stigma und soziale Unterstützung haben, trotz Anbindung an ein multidisziplinäres Team mit kostenloser, zeitnah begonnener ART. Es braucht weitere Untersuchungen, um ungestillte Bedürfnisse dieser Patientenpopulation zu identifizieren und die effektive Implementierung multidisziplinäre Versorgungsmodelle zu verstehen.

Abstract

Context: Psychosocial challenges (e.g., poor mental health) hinder engagement at each step of the HIV Care Cascade for people living with HIV (PLWH). Multidisciplinary HIV care models with dedicated resources for mental health support, alongside free and rapid antiretroviral therapy (ART) initiation may attenuate psychosocial issues. To date, little research has explored changes in mental health and associated factors of PLWH while engaged in such a care model.

Objective: To assess psychological distress, perceived HIV related stigma, and perceived social support while enrolled in multidisciplinary care with cost-covered and rapid ART initiation.

Study Design: 96-week mixed-method prospective cohort study in a quaternary hospital-based HIV clinic. Care was provided by a multidisciplinary team composed of onsite physicians, nurses, social workers, clinical pharmacists and a psychiatrist. ART was provided free of charge on site and as soon as possible (ideally within 7 days) after linkage to care.

Population Studied: Newly diagnosed PLWH recruited since January 2020. As of June 2022, 39 PLWH were enrolled, most are male (n=32, 82%), migrants (n=30, 77%), unemployed (n=23, 59%), and have at least a college-level education (n=25, 64%).

Instruments: Three patient reported outcome measures (PROMs) were administered at weeks 4, 24, 48, and 96: (1) Kessler Psychological Distress Scale 6-item version (score range 6-30; scores between 19-30 indicate probable to serious mental illness); (2) Internalized AIDS-Related Stigma Scale (score range 0-7; higher scores indicate greater perceived stigma); and (3) Medical Outcomes Study Social Support Survey (score range 0-100; higher scores indicate greater perceived social support). Descriptive statistics and linear mixed model analyses were reported.

Results: At the four time-points, average scores ranged from: 22.0-25.6 (SD range: 4.0-6.8) for psychological distress; 3.9-5.2 (SD range: 2.1-2.3) for internalized stigma; and 48.8-59.7 (SD range: 28.7-36.0) for perceived social support. For all PROMs, no significant differences were found over time and by sociodemographics at enrollment.

Conclusion Preliminary results showed that, irrespective of sociodemographics and time enrolled, PLWH continue to face challenges with mental health, stigma and social support, despite engagement in multidisciplinary care with free and rapid ART initiation. Further

research is required to understand unmet psychosocial needs of PLWH and how multidisciplinary care pathways unfold in real-world contexts.

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Abbreviations

MMH	Menschen mit HIV
HIV	human immunodeficiency virus
PLWH	people living with HIV
ART	antiretroviral therapy
HrQoL	health-related quality of life
PROMs	patient reported outcome measures
ASAP study	Antiretroviral Speed Access Program study
B/F/TAF	bictegravir, emtricitabine and tenofovir alafenamide
K6	6-item Kessler Psychological Distress Scale
IA-IRSS	Internalized AIDS-Related Stigma Scale
mMOS-SSS	modified Medical Outcomes Study Social Support Survey
LGB	lesbian, gay or bisexual
LGBTQ+	lesbian, gay, bisexual, transgender, and queer (or questioning), plus other sexual and gender identities

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1 Introduction

Health care for people affected by the Human Immunodeficiency Virus (HIV) has evolved tremendously over the past two decades. Having been an infectious disease with poor prognosis and limited treatment options, HIV infection has now become a chronic disease, as a result of major advancements in antiretroviral treatment (ART). People living with HIV (PLWH) now see a substantially improved life expectancy, approaching that of the general population (1, 2).

Despite these biomedical advances, PLWH are still disproportionately burdened by comorbidities (e.g., cardiovascular disease, cancer, osteoporosis)(3) and psycho-behavioural problems(4). Psychosocial challenges (e.g., poor mental health, lack of social support) remain major issues, affecting engagement with care and treatment [4], and ultimately the health outcomes of PLWH (5).

Optimal health outcomes for HIV patients are achieved by ensuring they are successfully diagnosed, connected to, and retained in HIV care. These stages are conceptualized in the HIV Care Continuum, which describes these steps as necessary for achieving viral suppression(6). An undetectable viral load is vital for the improvement of health and life expectancy of these patients, as well as for reducing the risk of transmitting the disease to others to 0 (6).

Significant research and clinical effort has been focused on viral suppression to evaluate treatment outcomes in the field of HIV(7). While viral suppression is an essential component of treatment success, researchers have pointed out that it should not be the only marker for successful HIV care(8). Shifting the focus from merely biomarkers for HIV/AIDS like HIV viral load and CD4 T-cell count to parameters such as health-related quality of life (HrQoL), which may reflect a patient's wellbeing more wholistically, seems to be an important step towards comprehensive HIV care(8, 9).

HrQoL as a concept also includes socioeconomic variables (e.g., social networks, experiences of stigma, employment status) and multiple studies have shown that HrQoL of PLWH is lower in comparison to the general population, despite being virologically stable (10-12).

In the past, numerous studies have reported an association between psychosocial challenges, including the domains of depression, stigma, and social support, and poor HrQoL among PLWH (13-16).

Unmet psychosocial needs can have severe implications for the health outcome of PLWH (5). It is widely known that PLWH are disproportionately affected by psychiatric disorders, stigma and discrimination, when compared to the general population(4) These issues constitute significant barriers in the HIV care continuum for patients(4).

For example, depression, a condition affecting around 40-42% of PLWH, has been linked to poor health promoting behaviour(4, 17). The stigma, associated with having this chronic disease is known to potentially lead to hesitancy to undergo HIV-testing, poor adherence to treatment as well as decreased retention in care(18, 19). Difficulties with engagement in HIV-care and treatment adherence have also been associated with a poor social support system(20).

These are merely a few examples of the vast consequences that issues with mental health or social networks can have on the health of PLWH. With the goal of advancing long-term wellbeing of patients dealing with this chronic disease, quality care must also include consideration of psychosocial status of patients (8, 21).

To our knowledge, there is little data exploring outcomes of psychosocial measures in newly diagnosed PLWH in a multidisciplinary HIV care model, that is set up to provide programs and services (e.g., cost-free treatment and access to professional mental health support) with the potential to mitigate psychosocial challenges.

This paper will focus on assessing key psychosocial elements, namely mental health, HIV-related stigma, and social support, in PLWH engaged in medical care, to attain a better understanding of the landscape and provide data to help orient future efforts in establishing optimal care models for PLWH.

2 Psychosocial Issues and HIV

2.1 Mental Health

Mental health issues have a major relevance in HIV care because they have been shown to negatively impact every step of the HIV care continuum. Diagnosis, initiation of ART, and treatment adherence are all affected by the poor health behaviours, associated with psychiatric disease (4, 17, 22). Struggling with anxiety, for example, might make it difficult to engage in health promoting behaviour, and depressive symptoms have been associated with poor self-management activities necessary for treatment adherence(23, 24). Furthermore, poor mental health is known to exacerbate socioeconomic barriers to linkage and retention in HIV care (4).

Literature clearly shows that PLWH are disproportionately affected by mental health problems, such as depression and anxiety, especially marginalized groups including migrants and gay and bisexual populations (4, 25, 26). It is estimated that on average, 40% to 42% of PLWH suffer from depression, which is about 2-4 times higher relative to the general population(17). Illicit drug use was identified in 40% of PLWH and 15% meet criteria for hazardous or heavy alcohol consumption. In contrast, in the general US population, numbers show that 10% engage in illicit drug use and 6.5% in heavy drinking(27).

The interconnection between depression and HIV is complex. On one hand, depressive symptoms are associated with an increased risk for HIV infection (e.g., by increasing HIV risk behaviour), while, on the other hand, HIV itself can lead to depression via neurobiological mechanisms (resulting from the viral infection of the brain), or also as a consequence of psychosocial stressors arising from having the disease(17). Such stressors include stigma related to disclosure of HIV status to co-workers or family, the prospect of having to deal with a chronic disease as well as possible comorbidities, treatment side effects, and potential functional disabilities influencing relationships and daily life (e.g., sexual dysfunction)(17).

Past research has also demonstrated a higher prevalence of anxiety in PLWH relative to non-infected individuals(22). For example, a study including 2863 participants, performed in 2014, reported symptoms of anxiety in 33% of PLWH screened in western Europe and Canada(28). A systematic review from the same year found that prevalence of anxiety ranged from 4.4-18.1% in the general population, while PLWH on ART had much higher rates (28.4% mean point prevalence; SD 17.07). In addition, when compared to people suffering from other chronic conditions, HIV infected individuals seem to have a higher risk of developing anxiety (5). Factors that have been linked with higher levels of anxiety in PLWH include a CD4 count below 250 cells/µl, HIV-related discrimination, and internalized stigma(29).

2.2 Stigma

A unique feature that distinguishes HIV from many other diseases is the stigma and the resulting discrimination associated with having this condition(30). HIV is stigmatized more than other often devalued conditions such as mental health issues and physically visible chronic diseases(31). Many still have negative judgements and prejudices about who is likely to get the disease, and outdated beliefs about transmission and the fear of getting HIV continue to prevail(32).

Numerous studies have documented the great burden of stigma PLWH experience(5, 27, 33, 34). As an example, a systematic review found that among PLWH on ART, 42% to 83% experience stigma. This review included stigma experienced through discrimination from friends, family, and community, as well as internalized feelings of stigma (e.g., poor self worth connected to one's HIV diagnosis)(5).

It is important to note that the term stigma is used to describe a multidimensional construct, which researchers have conceptualized and divided into interpersonal, and intrapersonal (or internalized) experiences of stigma. Interpersonal stigma describes enacted discrimination directed towards an individual from another person or group. Intrapersonal stigma is a term used for internalized negative feelings about oneself or the stigmatized condition resulting from experiences of discrimination (18, 34).

Stigma is a widely recognized barrier to health integrity of PLWH(27, 33). Problems with stigma negatively affect readiness to undergo HIV testing (the associated anticipated stigma might deter people from getting tested for HIV(19)), adherence to ART and retention in care (18). In addition, stigma in the health care setting continues to impact health care delivery(33). The 2020 paper by Yuvaraj et al. describes the use of unnecessary personal protective equipment by medical staff, referral of patients to specialists delaying access to care, as well as derogatory verbal interactions as contributors to a stigmatizing environment(33). These are just a few examples of behaviours adding to experiences of stigma for PLWH in healthcare settings.

Discrimination and stigma also remain relevant issues even in people who have achieved an undetectable viral load, particularly affecting marginalized populations (8). PLWH may have to deal with multiple stigmatized identities (e.g., socioeconomic status, gender, race) exacerbating their experience of stigma. For example, people of color in the US have been shown to experience more HIV-related stigma compared to white PLWH(34). The interplay of several stigmatized identities in minority groups might explain why viral suppression might not suffice to mitigate experiences of stigma and discrimination. In their mixed methods study from 2022, Semler et al. found that even after living with HIV for decades, participants perceived significant HIV-related stigma(34). Many patients reported having lost relationships to loved ones after disclosing their HIV status, making them socially isolated(34).

Many psychopathological consequences have been linked to experiences of stigma in PLWH such as stress, anxiety, and depression (4, 18, 29). Furthermore, the discrimination resulting from HIV-related Stigma often causes or aggravates issues with social isolation and support (5). Results from a longitudinal cohort study performed in rural Uganda, including 422 HIV infected individuals on ART, suggest a bidirectional relationship between stigma and social support. For study participants, lacking social support was associated with greater stigma and stigma was correlated with an impaired ability to access social support (18).

2.3 Social Support

With all the necessary steps in mind to achieve viral suppression, PLWH find themselves having to navigate complex processes in the health care system. Social support becomes relevant throughout this journey, as it may provide help emotionally (e.g., social relations showing concern about one's HIV diagnosis), instrumentally (e.g., having financial aid for health care coverage), as well as informationally (e.g., advice and information on options within the healthcare system) (35).

The Steps Study, a prospective cohort study from Texas, examined the potential association between perceived social support and outcomes at each step of the HIV care continuum, for newly diagnosed PLWH. Results indicate that greater social support promotes more timely diagnosis, better linkage to care and increased treatment adherence (36). Furthermore, social support also seems to have a protective effect against experiencing HIV related stigma (37).

Contrarily, not having a social support system seems to be an obstacle to successful HIV treatment. A mixed methods study from the US observed participants with difficulties with engaging in HIV care and treatment adherence. Reports of levels of social support were low in all of these and more than half mention experiencing extreme isolation, suggesting that lack of social support may be an indicator for poor treatment outcome (20).

A study performed in Switzerland showed that perceived social support in PLWH was linked to better outcomes for Health-related quality of life, while the opposite was true for patients lacking social support (38). Basic needs such as housing, food and financial security are closely connected to health-related needs of HIV patients. Being at a socioeconomic disadvantage makes people more vulnerable to acquiring HIV and negatively impacts health outcomes (30).

This evidence suggests that, alongside psychosocial issues related to mental health and HIV related stigma, it is vital to also consider patient's social support status as an essential influencer for health outcome for PLWH.

3 Patient Centered Care

Patient centered care looks at each patient individually, not only limiting them to their diagnosed disease, but also considering their social needs, psychological wellbeing and the environment they are embedded in(39). With this vision, providing quality care encompasses responding to all these components wholistically, when approaching treatment provision.

In Washington, D.C., Felizolla et al. have studied the transformation of a patient-centered HIV practice for Latinx patients. With adaptations in the primary care practice (e.g., culture specific training for staff members, incorporating patient centricity into the workflow), they observed an improvement in retention in care, compliance, and viral suppression for HIV patients(40).

Patient centered care, however, goes beyond these traditional markers for HIV-related health outcomes: Experts agree that considering HrQoL of PLWH in health care systems is an important component in achieving patient centricity and promoting the long term well-being of patients(8). In 2017 the European Parliament published new recommendations for chronic HIV care, with a focus on the long-term health of PLWH(41). With the evolving efficacy of antiviral HIV treatment, HIV no longer needs to be considered a fatal condition(1). Having a long life expectancy, however, can not be equated with having good health and quality of life(42). The *HIV Outcomes recommendations* therefore emphasise "adopting an integrated, outcomes-focused and patient-centred approach to long-term HIV care" (41).

This recommendation implies ensuring access to health services beyond HIV treatment alone, by integrating services to manage comorbidities, including mental health conditions. Such multispecialist care needs a structured approach. For each patient, ideally, a coordinator should be designated, and a personalized care plan established, to holistically address individual needs of the patient (41). Choice of a suitable care model becomes an important consideration. Long-term HIV care is increasingly becoming the role of primary health care providers. Service integration into primary care seems to be a feasible approach for meeting challenges of PLWH that go beyond achievement of viral suppression (30).

4 Multidisciplinary Care Model

A model of care that has the potential to adapt to individual needs of patients is the multidisciplinary care model(43). The multidisciplinary care approach means that care is provided by a team, consisting of professionals from various disciplines, working together to pursue a shared goal. Multidisciplinary HIV care has shown to potentially improve retention in care, treatment initiation and adherence for HIV patients (44-46). Furthermore, data suggests that having a pharmacist and/or services providing mental health aid integrated into the care team, increases the likelihood of achieving an undetectable viral load (44, 47, 48). A study conducted over a six-year period in the US showed that care models with integrated psychosocial services were 3.1 times more likely to achieve an undetectable viral load than HIV primary care alone (47).

However, advantages are not limited to traditional steps of the treatment cascade. Multidisciplinary care models may mitigate psychosocial issues by, for example, providing easy access to mental health services and on-site social workers, which could aid in issues such as navigating health care coverage (43). Some studies specifically looked at mental health benefits associated with multidisciplinary care (43). An observational study performed in a tertiary HIV clinic, that had integrated psychiatric counselling available for patients, showed a significant decrease in self-reported depression scores for HIV patients after receiving depression counselling (49). Another study found that perceived stigma was reduced in HIV patients accessing mental health services embedded in HIV primary care (50).

5 Rapid Initiation Antiretroviral Therapy

The term rapid initiation ART refers to starting HIV treatment as soon as possible after confirmation of diagnosis, potentially even the same day (51). This kind of timely treatment initiation, has been shown to benefit linkage to care, reduce time to achieving an undetectable viral load and lead to better outcomes of care retention (52-54). Additionally, randomized controlled trials have shown better outcomes in sustained viral suppression and overall survival for patients who initiated treatment the day of diagnosis (55, 56).

These benefits have been observed even in populations including patients affected by psychosocial challenges (e.g., illicit drug use, major mental health conditions) (57). Stigma arising from possibly transmitting the virus, is decreased by minimizing time between infection with HIV and viral suppression. Furthermore, prioritizing easy and fast access to ART has the potential to counteract structural inequalities, that feed into vulnerable populations (e.g., those facing disproportionate socioeconomic barriers), having poorer outcomes (51).

These arguments support that systems should adopt this kind of ART. The World Health Organisation, in 2017, has published recommendations specifically for the use of rapid ART (58). Similarly, since 2019 the department of Health and Human Services recommends the initiation of early ART in to promote health outcomes in PLWH (59).

Same-day ART initiation, however, requires the mobilisation additional resources within the health care structure (e.g., extra staff members, additional funding) (51). This kind of treatment dispensation needs careful planning and coordination within a team of professionals from multiple disciplines. It is critical that there is a close working between testing sites and sites of treatment initiation, possibility for same-day clinician visits and close follow up (51). Meanwhile the multidisciplinary team must address patient-education (how to initiate medication and navigate ongoing treatment), management of insurance coverage, laboratory testing etc. (52).

This demonstrates, while the rapid initiation ART clearly has shown to optimize HIV-related outcomes, it is also quite resource intensive. In order to make this strategy feasible, availability of a multidisciplinary setting and resources at various stages (planning, execution) must be ensured.

6 Patient Reported Outcome Measures

An efficient way to realize patient-centered care is the use of so called patient reported outcome measures (PROMs), a means to quantitively assess self-perceived health status of patients and subjective experience of care, using questionnaires (60). Implementations of PROMs into routine care allows for a more holistic assessment of a patient's wellbeing:

Questionnaires may be directed towards various dimensions of care such as treatment satisfaction, health behaviours (e.g., sexual risk behaviour, substance abuse) and life circumstances (e.g. housing, nutrition) (61). It also facilitates patient-provider communication, the prioritization of concerns, and provider awareness of patient problems (61, 62). For example, administering PROMs pre-consultation can allow a more focused patient-provider interaction, with less time spent on information gathering (61). Furthermore, research has shown that detection and monitoring of symptoms by providers is improved, which is especially relevant for directly actionable domains, such as suicidal ideation or substance abuse (63). Moreover, the consideration of information reported by the patient, empowers them as partners in care and allows providers to prioritize individual concerns (61, 64). In addition, having questionnaires incorporated into routine care may mitigate barriers of disclosure of sensitive issues (e.g., at-risk alcohol use) and therefore facilitate an open conversation between patient and provider (65).

PROMs make it possible to shed light on clinically relevant issues, that are not easily observable or measured otherwise (e.g., mental health struggles, medication adherence, HrQoL)(61, 65). Paying attention to psychological and social problems of patients on ART is critical because of their close connection to HIV-related outcomes(4). Thus, with the trend towards advancing patient-centered care, PROMs find increasing relevance in the field of HIV(62). There is international consensus on the interest of integrating PROMs to inform HIV care and foster the long-term wellbeing of PLWH(8, 41). Evidence supports PROM use for HIV care, given its high acceptability and association with improved provider awareness, monitoring, treatment, and referral for important areas of HIV care(61).

The 2020 paper by Meghan Kall et al., specifically addresses the need for utilization of PROMs to provide quality care for PLWH. Promotion of widespread use of PROMs, however, necessitates further research, linking improvements in PROMs results to improved HIV care outcomes(62). The use of patient reports in research, as well as routine care, has the potential to help identify models that are best suited to meet needs of HIV patients (62). Establishment of PROMs in the field of HIV, therefore, appears to be an important step on the way to comprehensive, quality care with a patient-centered approach.

7 Materials and Methods

7.1 Research Question

This study aims at assessing psychosocial outcomes for newly referred, treatment naïve, patients enrolled in multidisciplinary HIV care with free antiretroviral therapy, provided as soon as possible after linkage to care in a public hospital-based HIV clinic.
Specifically, psychological distress, perceived HIV-related stigma, and perceived social support will be assessed.

In addition to this main objective, the following questions will be investigated:

- Is there any change in score outcome for psychological distress, perceived HIV-related stigma and perceived social support over time?
- Are there any potential associations between psychosocial outcomes over time and sociodemographic background at enrollment?

7.2 Design

This study is a subset of an ongoing larger study, the Antiretroviral Speed Access Program (ASAP) study, evaluating HIV patient care in a multidisciplinary model with a predominantly migrant population. In this prospective cohort study, newly referred and treatment-naïve HIV patients are followed over 96 weeks, in a quaternary HIV clinic in Montreal, The Chronic Viral Illness Service at the McGill University Health Centre.

Care is provided by a team comprised of a physician, nurse, social worker, pharmacist, and psychiatrist on site. The antiretroviral treatment, is a combination of 3 antiretroviral in the form of a one tablet regiment (single treatment regimen STR), bictegravir, emtricitabine and tenofovir alafenamide (B/F/TAF; Biktarvy©), was provided free-of-charge and as soon as possible after linkage to care, qualifying it as rapid ART.

The study was initiated in January 2020. This thesis paper reports data from 39 participants, collected up until June 2022. Participants were included in the ASAP study with the precondition of meeting the following criteria:

7.3 Inclusion Criteria

1) Adult, 18 years of age or older, infected with HIV 1, newly referred to the study clinic.
2) Treatment-naïve, meaning having not received any anti-HIV therapies, except for pre-exposure prophylaxis or post exposure prophylaxis, up to 30 days before screening.
3) Estimated glomerular filtration rate (eGFR) >30 mL/min/1.73m2
4) For heterosexual men: Use of minimum one barrier method for contraception.
5) For female participants: use of a method birth control acceptable while taking B/F/TAF. (This criterion was set up due to lack of information on drug effects during pregnancy and breastfeeding.)

Patients were not eligible for study participation when one or more of the following criteria applied:

7.4 Exclusion Criteria

1) An eGFR of < 30 mL/min;
2) Patient with an active pregnancy, breastfeeding or trying to conceive or likely to be pregnant.
3) Participation in another study examining HIV drug intervention during the study period.
4) Participation in any other investigative study using oral medications.

7.5 Data Collection and Instruments

Data were collected from the hospital's electronic patient file system, reporting sociodemographic data of patients and score outcomes of the administered PROMs. These PROM scores, evaluating psychosocial parameters, were collected in the form of questionnaires, and administered verbally by trained interviewers, at week 4, 24, 48 and 96. Optionally, if preferred by the patient, PROMs could also be filled out by patients on their own or together with a relative or friend.

Psychological distress was examined using the 6-item Kessler Psychological Distress Scale (K6). Patients are asked to indicate frequency of experiencing specific emotions in the last month on a 5-point Likert type response scale ranging from “All of the time” to “None of the time”. Sum scores add up to form a range of 6-30, where scores of 19–30 indicate probable Serious Mental Illness (66). Cronbach’s alpha for this scale was calculated to be 0.86 (67, 68).

HIV-related stigma was evaluated with the 6-item Internalized AIDS-Related Stigma Scale (IA-IRSS). Patients were asked to answer either agree = 1 or disagree = 0, to questions about difficulty disclosing their HIV status or feelings of guilt associated with it. Sum scores ranged from 0-6 with higher scores representing greater internalized stigma. The range for Cronbach’s alpha is 0.73 to 0.76 (69).

The modified Medical Outcomes Study Social Support Survey (mMOS-SSS) was administered to measure social support. This 8-item measure is divided into two 4-item subscales, separately evaluating instrumental and emotional support. Average scores for subscale items are calculated and transformed to form a range from zero to 100 for possible scores. Higher score represents more social support. Cronbach’s alpha ranges from 0.88 to 0.93 (70).

7.6 Data Analysis

Patient data were analyzed using a quantitative approach. Descriptive statistics and linear mixed model analyses were performed to examine possible impact on variation of PROM values over time and by sociodemographic factors (i.e., Immigration Status, Migrant Status, Age, Gender, Sexual Orientation, Highest Education Level, and Occupation*)*. Sociodemographic data were converted to binary variables (Table 1.). The linear mixed model approach was chosen as it is suitable for evaluating longitudinal studies, where measurements are repeated over time. Further it makes it a flexible analytic tool, as it allows for incomplete datasets to be incorporated into measurements and can effectively be applied to small sample sizes (71, 72).

Immigration statuses were grouped to best represent similarities in health care coverage. In each model combinations of three variables out of the potential factors were included. The model with the lowest AIC was chosen. For statistical analysis the IBM SPSS Statistics program was used. The Significance Level was set at $\alpha < 0.05$.

Table 1. Binary Categories for Linear Mixed Model Analysis

Variable Name	Group 1	Group 2
Immigration Status	citizen, refugee, asylum seeker	temporary status, no resident status
Migrant Status	migrant	non-migrant
Age	below average age	average age or older
Gender	male	female
Sexual Orientation	heterosexual	LGB
Highest Educational Level	pre-college	college or university
Occupation	unemployed	paid-employed

7.7 Ethics

The research Ethics Board from the McGill University Health Centre committee approved of the conduction of the study (number MP-37-2020-4911). Measures of the study were performed in accordance with Declaration of Helsinki, International Conference on Harmonization Good Clinical Practice Guidelines and Health Canada regulations. All study participants have given informed consent.

8 Results

This paper presents preliminary results of 39 participants enrolled between January 2020 and June 2022. A total of 39, 25, 19 and 5 patients have responded to PROMs at week 4, 24, 48 and 96 respectively.

8.1 Sociodemographic Status at Enrollment

At enrolment, median age was 34 years with a range of 23-71. Most of the 39 participants were: male (n=32, 82.1%); migrant (n=30, 76.9%); and unemployed (n=24, 61.5%); self-identified as lesbian, gay, or bisexual (n=19, 48.7%); and had at least college level education at enrolment (n=25, 64.1%) (Table 2.).

Table 2. Sociodemographic Characteristics of Participants at Enrolment

Baseline characteristic	*n*	%	*median*	average	range
Age (y)	-	-	34	39	23-71
below average	22	56.4	-		
average or older	17	43.6			
Gender					
male	32	82.1			
female	7	17.9			
Migrant Status					
migrant	30	76.9			
non-migrant	9	23.1			
Immigration Status					
citizen	12	30.8			
asylum seeker	13	33.3			
refugee	2	5.1			
temporary	12	30.8			
Sexual Orientation					
heterosexual	11	28.2			
LGB [a]	19	48.7			
no answer	9	23.1			
Highest Educational Level					
pre-college	14	35.9			
college or university	25	64.1			
Occupation					
unemployed	24	61.5			
paid-employed	13	33.3			
no answer	2	5.1			

[a] Lesbian, Gay or Bisexual

8.2 Psychosocial Outcomes

Average Score outcomes of PROMs at weeks 4, 24, 48 and 96 respectively were as follows (Table 3.):

Scores for the **Kessler Psychological Distress** Scale resulted in an average of 22.3, 24.5, 25.6, and 22.0 (SD = 6.8, 6.1, 5.7, and 4.0, respectively). Average scores for **Internalized AIDS-Related Stigma Scale** were 4.5, 4.0, 3.9, 5.2 (SD = 2.1, 2.3, 2.2, and 2.2, respectively). Average scores for **Perceived Social Support** Score were 53.8, 55.2, 48.8, 59.7 (SD = 28.7, 29.0, 36.0, 31.3, respectively). For all PROMs, no significance was found examining change of scale scores over time and when adjusted for sociodemographic status. Table 4. shows results for mean scores over all time points for all PROMs by sociodemographic variables.

Table 3. Psychosocial Outcomes

	Week 4	*Week 24*	*Week 48*	Week 96
Number of Participants	39	25	19	5
Psychological Distress				
Average scale score	22.3	24.5	25.6	22.0
SD of average score	6.8	6.1	5.7	4.0
Internalized AIDS related Stigma				
Average scale score	4.5	4.0	3.9	5.2
SD of average score	2.1	2.3	2.2	2.2
Perceived Social Support				
Average scale score	53.8	55.2	48.8	59.7
SD of average score	28.7	29.0	36.0	31.3

Table 4. Mean Scores for PROMs by Sociodemographic Variable

Baseline characteristic	K6 [b]		IA-IRSS [c]		mMOS-SSS [d]	
	average	SD	average	SD	average	SD
Age (y)						
below average	23.6	6.3	4.3	2.2	53.5	30.3
average or older	24.6	5.9	4.1	2.3	57.0	30.8
Gender						
male	23.6	6.3	4.3	2.2	53.5	30.3
female	24.2	6.0	4.2	2.3	59.0	29.4
Migrant Status						
migrant	23.9	6.3	4.3	2.2	54.0	30.7
non-migrant	23.5	6.8	4.1	2.0	51.5	31.2
Immigration Status						
citizen	23.7	6.4	4.2	2.2	54.5	30.8
asylum seeker/refugee	23.9	6.2	4.2	2.4	60.3	29.5
temporary	23.9	6.3	4.3	2.2	54.0	30.7
Sexual Orientation						
heterosexual	24.6	5.9	4.3	2.2	56.0	31.2
LGB [a]	23.6	6.4	4.3	2.2	53.4	30.4
no answer	23.6	6.4	4.2	2.2	54.3	30.7
Highest Educational Level						
pre-college	23.6	6.4	4.2	2.2	54.2	30.5
college or university	23.6	6.4	4.3	2.2	53.4	30.4
Occupation						
unemployed	23.6	6.4	4.2	2.2	54.2	30.6
paid-employed	23.6	6.3	4.3	2.2	53.5	30.3
no answer	24.1	6.6	4.3	2.1	53.1	31.8

[a] Lesbian, Gay or Bisexual, [b] 6-item Kessler Psychological Distress Scale,
[c] Internalized AIDS Related Stigma Scale,
[d] modified Medical Outcomes Study Social Support Survey

9 Discussion

The purpose of this study was to perform a preliminary assessment of psychosocial outcomes for treatment naïve HIV patients receiving care in a multidisciplinary care model with free treatment, rapid initiation ART. Results demonstrate that psychosocial problems like poor mental health, internalized HIV-related stigma and lack of social support, remain issues in this study population. Results did not identify significant variation of score results over time and based on sociodemographic background.

All participants included in this study had scores for psychological distress that indicate probable to serious mental illness. This finding supports previous research indicating a high prevalence of mental health challenges in PLWH populations. Results of the IA-RSS suggest that participants were experiencing above average levels of internalized stigma. As has been demonstrated in a previous study, higher scores in the IA-RSS have been strongly correlated with poor mental health. In that study, performed in four different countries, mean scores for PLWH ranged from 2.06-3.84 (73). In comparison, this study population has achieved an even higher score range (mean score range 4.5-5.2, across the four time points. With this cohort average scale scores for Social Support across the four time points ranged from 54-60. In comparison to the general US population, where score average for the scale was found to be 70, this study population achieved lower results. This could indicate that in general, patients included in this study have more issues with social support compared to the general population (20).

Several factors might contribute findings of low social support scores: First, Patient demographics show that over 75% of participants were migrants. Many have only recently immigrated into Canada and building a personal support network might be difficult with potential language and cultural barriers. Second, most patients were male, which might be relevant due to possible gender specific tendency to cope with psychological burden and setbacks. Though this preliminary analysis did not find significant differences based on gender, a study evaluating social support status of PLWH in China found lower scores of social support in men as opposed to women, and suggested they might be less likely to open up to others about their experiences(74).

Third, poor mental health (as has been highly prevalent in this population) and low self worth might contribute to perceptions of loneliness and behaviours feeding into social isolation(75). Fourth, the present or anticipated HIV-related stigma might hinder establishment of personal relationships and consequently access to community support.

Analysis further showed that there was no significant change over time in PROM outcomes. This raises the question of whether there are unmet needs for PLWH in this care model. However, it is not possible to draw conclusions given the limited number of participants that have completed all study follow-ups. Further research taking a qualitative approach to explore patient experience might shed more light on care gaps of this patient population.

Arora et al. conducted a qualitative study interviewing 16 patients from this ASAP study cohort, to longitudinally assess experience of care of migrant people living with HIV. They found that all participants faced psychosocial challenges beyond their HIV status, during linkage or while being engaged in the HIV care cascade. Participants expressed having problems with obtaining legal status in the new country, dealing with financial insecurities, social isolation, as well as having difficulty integrating into the local society (76). Such stressors might have significantly impacted score outcomes.

Many of the participants entered Canada only a few months before study enrolment. Migration is a process that often means facing stressors like uncertainty with respect to living circumstances, income, and legal status (77). Migrants, both with and without the condition of HIV status, are more vulnerable to developing psychiatric disorders or carrying a higher mental health burden, compared to other populations (78, 79). Furthermore, it is documented that LGBTQ+ migrants, which comprised a majority of this study population, tend to be an at-risk population for significant psychological distress, as they often have to face discrimination and marginalization due to their intersecting identities (80).

Another relevant factor beyond HIV that might have played a considerable role in score outcomes is that the COVID-19 pandemic coincided with the conduction of this study. At the beginning of the pandemic, Chenneville et al. predicted that increased stress and fear of COVID-19 would lead to poorer mental health outcomes and that social isolation would be a consequence of measures taken during that time (81). Social distancing, which was a prevention strategy during the pandemic, is known to impact mental and physical health outcomes (82). Studies have observed significant mental health issues and difficulties navigating relationships during the COVID-19 pandemic (83).

In summary, results indicate that PLWH continue to face psychosocial challenges while receiving care in this setting. This may suggest that there remain unmet needs, despite engagement in a multidisciplinary HIV care model. Findings from other studies indicate that this study population may be facing psychosocial challenges that go beyond their HIV status. Additionally, results might have been significantly impacted by stressors and social challenges linked to the COVID-19 pandemic.

10 Limitations

Results must be interpreted with caution, as there are many limitations to this study. Firstly, this study presents preliminary results. Only 5 out of the 39 participants have completed all 96 weeks. Trend of score results and significance may be different after completion of the study by all participants. Interviews conducted with this cohort for another study did find an improvement over time in how comfortable patients felt navigating health care services (76). Familiarity with the care team structure might improve their ability to seek needed support, and consequently impact PROM outcomes. With more participants completing the final interview, a dynamic in results over time could potentially be observed.

Secondly, it is not documented how often a patient saw specific members of the care team (e.g., social worker, psychologist). While some patients might not have sought out support services, others could have significantly profited from multidisciplinary care team. Results do not differentiate between frequency and kind of support received in clinic.

Thirdly, generalizability of findings is limited, as there is a relatively small number of participants in this study cohort. To mitigate the issue of small sample size, linear mixed methods were utilized for analysis which are well suited for such longitudinal studies and remain robust even with limited samples. Also, participants were included in this study based on whether they met inclusion criteria after having been referred to the study site. This non-probabilistic sampling further limits generalizability. The study population was comprised of mostly male migrants, of which a majority identified as lesbian, gay or bisexual. This makes a relatively homogenous group and is not representative of other populations.

Lastly, with this study designs, only change over time and sociodemographic background were investigated for potential correlations of score outcomes. There are however several factors that could have considerably impacted score results. A potential contributor to psychosocial challenges is the fact that the conduction of this study coincided with the COVID-19 pandemic. In addition to the stressors brought about by living through a pandemic, care provision had to be adapted to meet regulations for social distancing (e.g., telecommunication, limiting number of staff members on site). In times of travel restrictions, the consequently more complex immigration process meant an additional burden to the work of social workers and nurses, further limiting resources of the care team.

11 Observations from Experiencing Multidisciplinary Care in Real World Contexts

An interesting point to further explore is how multidisciplinary care teams unfold in real world contexts. While this was not studied specifically here, the following paragraph mentions concerns raised in discussion with the care and research team of this study:

Having a theoretically sound concept of a multidisciplinary care model alone does not guarantee that real life settings allow exact implementation of it. For example, even if there is a social worker on the team, they might not be present enough hours per week, to be able to provide necessary support for all patients. This is just one example of how resources might be limited. Knowing how often the patient consulted a specific care team member (e.g., social worker or pharmacist), might be relevant when exploring associations of psychosocial outcomes and multidisciplinary care. There have been studies looking at optimal care team composition for maximizing ART adherence (84). Research, determining optimized multidisciplinary care team composition for improved psychosocial outcome could be of interest.

Another important point raised was the variability in an individual patient's understanding of the care team. Patients might not understand what a multidisciplinary care team is and what kind of support is available to them. This might be especially true for migrants, who enter an entirely new health care system. In this study, interviewers mentioned making an effort to continually remind participants of the functioning of the care team and what resources they have access to. This showcases that communication between the patient and care team, concerning the nature of multidisciplinary design, might be an essential factor for increasing quality of care provision.

Lastly, communication among care team members concerning PROM outcomes, appears to be an important consideration. Adaptations in the structure of care in response to score results can only be undertaken if the care team is informed about PROM outcomes (and the potentially discovered care gaps). Results should ideally be communicated among all members of the health care team, to aid the pursuit of improving care services.

12 Implications for Clinical Practice and Further Research

This paper presents preliminary results from a strictly observational study, and only allows very limited generalizations about outcomes for other populations. In order to make more general statements, future studies, investigating and contrasting psychosocial outcomes for differing HIV care models may be of interest. This could show potential benefits of multidisciplinary care with free, rapid ART in comparison to other approaches.

An additional area of future research to consider, is putting these PROM outcomes into context. Correlating data with events in the HIV care cascade by considering time to initiation of treatment and achieving an undetectable viral load, may reveal potential associations with score results.

In this study, the use of PROMs was a feasible approach to assess psychosocial parameters of HIV patients. However, interpretation of score outcomes and possible implications for care provision might not always be clear. Having concrete recommendations or guidelines would promote establishment and effective use of PROMs in HIV care. As PROMs find increasing relevance in patient centered HIV care, reports of experiences from clinicians implementing PROMs will hopefully shed more light on how these measures could guide everyday practice of health care providers.

An interesting question to investigate further would be how patients in this care model perceive their HrQoL, despite the psychosocial challenges they might deal with. HrQoL can also be systematically quantified with the use of PROMs(8). Previous research has consistently shown a link between HrQoL and psychosocial issues like depression, stigma and social support(13).

For example, higher levels of depressive symptoms have been shown to be correlated with lower levels of HrQoL in PLWH compared to PLWH without this symptomatology(85). A study performed in Finland with 440 PLWH, showed that severe stigma was correlated with significantly decreased HrQoL(15). Another systematic review further supports this notion by reporting that HIV-related stigma was associated with significantly lower HrQoL(16). Contrarily, there was a significant positive association between good social support and HrQoL, as observed in this systematic review looking at PLWH on ART in Ethiopia(14).

From this data, it seems clear that struggles with depression or lack of social support are closely tied with problems in HrQoL. However, researchers emphasize that further observational research, exploring mediators between psychosocial challenges and HRQoL, are needed to develop and investigate the efficacy of already existing support interventions (16).

In addition, studying how specific psychosocial interventions may mitigate challenges in these domains could be a further step towards optimizing support for patients living with this complex chronic disease. Assessment of HrQoL in this patient population would add another dimension to the evaluated aspects of health. With these prevailing psychosocial challenges, finding out about how patients respond to and cope with them can be valuable information for care providers and enable them to respond better to potential needs of PLWH.

13 Conclusion

This study preliminarily assessed psychosocial status of HIV patients by using PROMs for psychological distress, internalized HIV related stigma and perceived social support. HIV patients in this study, irrespective of sociodemographic status, continue to face challenges with stigma, mental health, and social support while engaged in multidisciplinary care with free and rapid antiretroviral treatment initiation. Further research is needed to explore possible correlations between psychosocial outcomes and how with how multidisciplinary models unfold in real-world contexts. This might reveal unmet needs of patients and identify opportunities to optimize HIV care.

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Appendix

Results of this study were submitted in the form of an abstract at the North American Primary Care Research Group (NAPCRG) 2022 conference under the category “research in progress”. After being accepted, results were presented at the annual conference in November 2022. The aim was to convey the following learning objectives:

On completion of the presentation, participants should be able to:

- Recall and identify several validated instruments that can be used to evaluate for specific psychosocial constructs.
- Understand the importance of not finding a significant difference in scores over four time-points across 96-weeks or by socio-demographic status.
- Understand the importance of quantitative and qualitative approaches for exploring and addressing mental health challenges in primary HIV care.

The poster presented at the conference is included in the appendix.

13.1 Poster

Longitudinal assessment of psychosocial outcomes for patients in multidisciplinary HIV care with rapid and free treatment

Lea Bischof[1-3]; Anish K. Arora[1,2,4,5]; Serge Vicente[1,6]; Edmundo Huerta[1,2]; David Lessard[1,2]; Kim Engler[1,2]; Nadine Kronfli[1,3]; Jean-Pierre Routy[3]; Marina Klein[3]; Joseph Cox[3]; Alexandra de Pokomandy[3,4]; Joel Ishak[1]; Lucas Delvallez[7]; Giada Sebastiani[3]; Benoit Lemire[8]; René Wittmer[9]; Isabelle Vedel[4]; Bertrand Lebouché[1-5]

1. Centre for Outcomes Research & Evaluation, Research Institute of the McGill University Health Centre, 2. Canadian Institutes of Health Research Strategy for Patient-Oriented Research (CIHR/SPOR) Mentorship Chair in Innovative Clinical Trials in HIV Care, 3. Chronic Viral Illness Service, McGill University Health Centre, 4. Department of Family Medicine, McGill University, 5. Infectious Diseases and Immunity in Global Health Program, Research Institute of the McGill University Health Centre, 6. Department of Mathematics and Statistics, Université de Montréal, 7. Faculty of Engineering and Health Management, University of Lille, 8. Pharmacy Department, McGill University Health Centre, 9. Department of Family Medicine and Emergency Medicine, Université de Montréal

1. Objective

To assess psychological distress, perceived social support, and perceived HIV-related stigma in patients enrolled in multidisciplinary HIV care with free antiretroviral therapy, provided as soon as possible after linkage to care.

2. Methods

- **Design:** 96-week mixed method prospective cohort study
- **Sample:** 39 patients recruited between Jan. 2020 and Jun. 2022
- **Approach:** 3 patient reported outcome measures (PROMs) administered at week 4, 24, 48, 96
  - (1) Internalized AIDS-Related Stigma Scale
    - Score range 0-7; higher scores indicate greater perceived stigma
  - (2) Kessler Psychological Distress Scale 6-item version
    - Score range 6-30; scores between 19-30 indicate probable to serious mental illness
  - (3) Modified Medical Outcomes Study Social Support Survey 8-item version
    - Score range 0-100; higher scores indicate greater perceived social support
- **Analysis:** Descriptive statistics and linear mixed model analysis

3. Results

- For internalized stigma, average scores ranged from: 3.9-5.2 (SD range: 2.1-2.3)
- For psychological distress, average scores ranged from 22.0-25.6 (SD range: 4.0-6.8)
- For perceived social support, average scores ranged from 48.8-59.7 (SD range: 28.7-36.0)
- No significant difference found for all PROMs over time, when adjusted for sociodemographic variables at enrollment

Table 1: Mean scores by week for PROMs and corresponding p-value

PROM	Week 4	Week 24	Week 48	Week 96	Sig[1]
Internalized AIDS-related Stigma					
Average Scale Score	4.5	4.0	3.9	5.2	p = 0.751
Standard Deviation	2.1	2.3	2.2	2.2	
Psychological Distress					
Average Scale Score	22.3	24.5	25.6	22.0	p = 0.633
Standard Deviation	6.8	6.1	5.7	4.0	
Perceived Social Support					
Average Scale Score	53.8	55.2	48.8	59.7	p = 0.963
Standard Deviation	28.7	29.0	36.0	31.3	

[1]Significance level α = 0.05

4. Conclusion

- HIV patients in this study, irrespective of sociodemographic status, continue to face challenges with stigma, mental health, and social support while engaged in multidisciplinary care with free and rapid antiretroviral treatment initiation.
- Exploring possible correlations between psychosocial outcomes with how multidisciplinary models unfold in real-world contexts might reveal unmet needs of patients in this care model.

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