Real World Community-Based HIV Rapid Start Antiretroviral with B/F/TAF versus Conventional HIV Antiretroviral Therapy Start – The RoCHaCHa Study, A Pilot Study

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Research Article

Keywords: HIV, ART, Rapid start ART, community-based health care, HIV viral load suppression

Posted Date: March 4th, 2024

DOI: https://doi.org/10.21203/rs.3.rs-3991888/v1

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Additional Declarations: Competing interest reported. During the study, author M.M. was on the speaker bureau for ViiV Healthcare and author W.V. was a speaker for Gilead Sciences. Author R.C. was a medical scientist who represented Gilead Sciences in this collaborative study. Authors J.S., A.Z., and M.M. were
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Abstract

Background

The rapid start of antiretroviral therapy (RSA) model initiates antiretroviral therapy (ART) as soon as possible after a new or preliminary diagnosis of HIV, in advance of HIV-1 RNA and other baseline laboratory testing. This observational study aims to determine if RSA with a single tablet regimen of bictegravir, emtricitabine, and tenofovir alafenamide (B/F/TAF) is an effective regimen for achieving viral suppression and accepted by patients at the time of diagnosis.

Methods

Adults newly or preliminarily diagnosed with HIV were enrolled from October 2018 through September 2021. Real world advantage, measured in days between clinical milestones and time to virologic suppression, associated with B/F/TAF RSA was compared to historical controls.

Results

All Study RSA participants (n = 45) accepted treatment at their first visit and 43(95.6%) achieved virologic suppression by week 48. Study RSA participants had a significantly shorter time (median 32 days) from diagnosis to ART initiation and virologic suppression, in comparison to historical controls (median 181 days) (n = 42). Qualitative feedback from study RSA participants showed high acceptance positive response to RSA.

Conclusions

RSA is feasible and well accepted by patients in a real-world community-based clinic setting. Promoting RSA in community-based clinics is an important tool in ending the HIV epidemic.

Background

Trillium Health (Trillium) is a community health center in Rochester, NY with a more than 30-year legacy of HIV prevention and treatment. Trillium serves about 850 people living with HIV and maintains several robust programs as part of New York State's initiative to End the HIV Epidemic (EtE)¹ and the national initiative, Ending the HIV Epidemic in the U.S. (EHE)², which highlight the importance of engaging and retaining people living with HIV (PLWH) in care. In January of 2017, Trillium began rapid start of antiretroviral therapy (RSA) for HIV treatment as standard of care. This treatment model initiates antiretroviral therapy (ART) the same day or as soon as possible after either a reactive rapid point-of-care HIV test or confirmatory HIV antibody test, in advance of HIV-1 RNA and other baseline laboratory testing.
RSA truncates the time from HIV diagnosis to ART initiation. Research has shown that RSA leads to improved clinical outcomes, including higher retention in care and viral suppression, as compared to the traditional model of ART initiation\textsuperscript{3 – 12}.

On February 8, 2018, a single tablet regimen of bictegravir, emtricitabine, and tenofovir alafenamide (B/F/TAF) was approved by the U.S. Food and Drug Administration (FDA) for treatment of HIV-1 infection\textsuperscript{13}. B/F/TAF is well-suited for RSA as it is one of few regimens that can be initiated without baseline laboratory results, supported by efficacy and safety data from pre- and post-marketing trials and is one of few regimens that can be initiated without baseline laboratory results\textsuperscript{14 – 16}. Still, some patients and providers may be hesitant to initiate treatment at time of diagnosis. The RoCHAChA study bolsters the current literature through real-world data quantifying the difference in patient outcomes as compared to older models of care, as well as qualitative data on patient experience and acceptance of RSA.

This observational study’s objectives are to 1) determine if RSA with a single tablet regimen of B/F/TAF is an effective regimen for suppressing HIV-1 RNA to undetectable levels, and 2) Assess patient acceptance of RSA at the time of diagnosis.

Real world advantage, measured in days between clinical milestones and time to virologic suppression, associated with B/F/TAF RSA was compared to historical controls. In addition, this study sought to identify areas of opportunity in the RSA workflow to shorten time to ART initiation and increase patient satisfaction with the RSA process.

**Methods**

All individuals who presented to Trillium with a new confirmed or preliminary HIV diagnosis from October 2018 through September 2021 were screened for this study. Participants were enrolled consecutively, had to be at least 18 years of age, treatment naïve, and presenting for treatment within 21 days of receiving their HIV diagnosis. Confirmatory laboratory results and resistance testing were not required for RSA initiation. Persons who were not eligible for study participation were still offered RSA. Participants underwent baseline assessment and began a single tablet regimen of B/F/TAF on the day of clinic presentation. Trillium's RSA process includes treatment adherence counseling, health insurance evaluation/navigation, management of social determinants of health, and onsite pharmacy and clinical laboratory services. Follow-up visits were conducted per protocol through 48 weeks at Trillium's main clinic location in Rochester, NY or via telemedicine.

The primary study endpoints include the proportion of patients who reached HIV-1 viral suppression to < 50 copies/mL within 48 weeks of ART initiation. Real-world treatment advantage was measured in days to clinical milestones, including median days from diagnosis to clinic presentation, from clinic presentation to ART initiation, and diagnosis to ART initiation. Time to virologic suppression was measured as median days from ART initiation to a viral load of < 200 copies/mL and < 50 copies/mL. The viral suppression endpoint of < 200 copies/mL is standard in the literature to represent
untransmissible status\textsuperscript{17}, and < 50 copies/mL is the typical clinical standard for virologic suppression\textsuperscript{18,19}.

The secondary endpoints include identification of barriers to initiation and adherence to ART, and participant acceptance of RSA. Participant feedback was collected through a questionnaire developed by the authors and administered at study completion, which asked about perceived barriers to medication initiation, attitudes about starting medication on the day of diagnosis or preliminary diagnosis, and potential interventions to improve the RSA process.

The control group was comprised of all patients of Trillium newly diagnosed with HIV who received standard of care ART initiation between January 2014 and August 2017, prior to RSA implementation at Trillium.

Treatment adherence and retention in care were assessed in the study group only. Treatment adherence was measured as proportion of days covered based on pharmacy dispense data\textsuperscript{20}. Retention in care was measured as the number of patients still on study at 48 weeks.

**Statistical Analysis**

Statistical analysis was completed using R programming\textsuperscript{21}. All continuous variables were analyzed using Kruskal-Wallis or Wilcoxon rank test. Fisher exact test was used to analyze categorical variables. A study size of 45 participants was deemed sufficient for a single-center pilot study, based on the number of treatment naïve PLWH who presented to Trillium in the preceding years. The historical control population size was made to be similar to the study size by reviewing how many newly diagnosed patients presented each month prior to RSA initiation at Trillium and selecting the date range that met our population size needs.

**Care Team**

A multidisciplinary team of providers, care managers, pharmacists, STI testing and prevention specialists, and clinical laboratory services collaborated to create a consistent approach to RSA for all patients. Initial rapid point-of-care HIV testing was performed by Trillium's STI testing specialists. These testing specialists complete thorough training and annual formal observations to ensure they are proficient at performing point-of-care HIV testing and are prepared to deliver results to patients.

The standard of care at Trillium includes care managers performing a comprehensive needs assessment during a new patient’s first visit to identify and address barriers to care and adherence. Care managers also connect patients with internal and community supportive services to address identified barriers. Internal supportive services available at Trillium include insurance enrollment and navigation, transportation assistance, food pantry access, and medication-assisted treatment (MAT). Community resources include legal aid services, employment services, and domestic violence programs.
An in-house pharmacy at Trillium provides same-day and mail delivered prescription medications. The pharmacists also monitor records of patients taking ART to ensure they have valid prescriptions for refills and have obtained their medications, providing another layer of adherence monitoring and support.

Having a clinical laboratory service which includes a phlebotomy center adjacent to Trillium's main clinic allows convenient access for patients.

**Clinical and Laboratory Evaluations**

Participants underwent clinical and laboratory evaluations at the time of enrollment and at subsequent follow-up visits according to the protocol in Appendix A, utilizing commercially available and validated assays. The rapid point-of-care HIV tests used are fourth generation (Determine™ HIV-1/2 Ag/Ab Combo immunoassay, Alere Inc.). The laboratory completes HIV-1 viral load quantification (COBAS 8800 system, Roche Diagnostics) and combined drug resistance and genotyping (GenoSure PRIme assay, Monogram Biosciences).

**Study Oversight**

The study protocol was reviewed and approved by an external accredited Institutional Review Board (IRB); WCG IRB (Puyallup, WA). Trillium contracted with a site management organization to manage study operations, maintain appropriate documentation, and report adverse events. All participants provided written informed consent and received compensation for their participation in the form of gift cards to local supermarkets.

**Screen Failures**

Participants had to complete at least one on-treatment visit and blood draw for viral load quantification to be included in statistical analysis. Some participants with false positive reactive tests (reactive rapid point-of-care HIV test with subsequent negative confirmatory testing) were noted. Those with negative confirmatory tests were instructed to stop taking ART and were removed from the study. All efforts were made to retain these patients in care at Trillium and initiate HIV PrEP when appropriate.

**Results**

**Baseline Presentation and Characteristics**

From October 2018 to September 2021, 75 individuals presented to Trillium with a new or preliminary HIV diagnosis and 60 individuals consented to be in the study. All 60 participants agreed to RSA with B/F/TAF during their first HIV appointment with a provider. Fifteen participants were excluded due to false reactive point-of-care tests (14) or transfer of care immediately after diagnosis (1), resulting in study size of 45 participants (Fig. 1).

Twenty-six participants received their diagnosis at Trillium, either during routine screening through primary care (10), STI testing or treatment (8), screening for PrEP (7), or an at-home HIV test provided...
through Trillium's remote testing service (1). Nineteen participants were diagnosed offsite through STI screening at an independent clinic or primary care office (7), an emergency department visit or hospital admission (5), the local Department of Health STI Clinic (4), a local university's health center (2), or an over the counter at-home HIV test (1).

There were no statistically significant differences in baseline characteristics between the study RSA and historical control groups (Table 1).

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Study RSA (n = 45)</th>
<th>Non-RSA control (n = 42)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at diagnosis, mean (SD)</td>
<td>31.7 (9.4)</td>
<td>37.7 (14.0)</td>
<td>0.093</td>
</tr>
<tr>
<td>Sex at birth = male, n (%)</td>
<td>43 (95.6%)</td>
<td>36 (85.7%)</td>
<td>0.148</td>
</tr>
<tr>
<td>Gender identity = male, n (%)</td>
<td>35 (77.8%)</td>
<td>33 (78.6%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Sexual orientation = gay, n (%)</td>
<td>26 (57.8%)</td>
<td>20 (47.6%)</td>
<td>0.394</td>
</tr>
<tr>
<td>HIV viral load prior to ART initiation, median (IQR), log₁₀ copies/mL</td>
<td>4.4 (3.8–5.1)</td>
<td>4.5 (4.1–5.1)</td>
<td>0.865</td>
</tr>
<tr>
<td>HIV viral load prior to ART initiation, median (IQR), copies/mL</td>
<td>49,158 (5,949 – 140,000)</td>
<td>31,500 (13,925 – 118,250)</td>
<td>0.865</td>
</tr>
<tr>
<td>HIV viral load prior to ART initiation &gt; = 100,000 copies/mL, n (%)</td>
<td>13 (28.9%)</td>
<td>12 (28.6%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td>25 (55.6%)</td>
<td>20 (47.6%)</td>
<td>0.523</td>
</tr>
<tr>
<td>Race = white</td>
<td>17 (37.8%)</td>
<td>18 (42.9%)</td>
<td>0.667</td>
</tr>
<tr>
<td>Race = black</td>
<td>1 (2.2%)</td>
<td>4 (9.5%)</td>
<td>0.154</td>
</tr>
<tr>
<td>Race = other</td>
<td>5 (11.9%)</td>
<td>7 (16.7%)</td>
<td>0.224</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td>31 (68.9%)</td>
<td>36 (85.7%)</td>
<td>0.077</td>
</tr>
<tr>
<td>Ethnicity = Non-Hispanic/Latinx</td>
<td>11 (24.4%)</td>
<td>6 (14.3%)</td>
<td>0.285</td>
</tr>
<tr>
<td>Ethnicity = Hispanic/Latinx</td>
<td>3 (6.7%)</td>
<td>0 (0.0%)</td>
<td>0.242</td>
</tr>
<tr>
<td>Ethnicity = unreported</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>1.000</td>
</tr>
<tr>
<td>CD4 cells/mm³ prior to ART initiation, median (IQR)</td>
<td>458 (285–652)</td>
<td>381 (289–552)</td>
<td>0.290</td>
</tr>
<tr>
<td>CD4 &lt; 200 cells/mm³ prior to ART initiation, n (%)</td>
<td>3 (6.7%)</td>
<td>5 (11.9%)</td>
<td>0.475</td>
</tr>
</tbody>
</table>

False Reactive Tests
Fourteen of the 60 (23.3%) consented participants who had reactive point-of-care tests were determined to be HIV-negative upon confirmatory testing. All fourteen participants discontinued B/F/TAF, and three (21.4%) patients initiated oral PrEP within seven days of receiving their confirmatory negative HIV-1 RNA test results. No adverse events were reported while these patients were on B/F/TAF in absence of an HIV infection.

**Treatment Initiation**

The median number of days between HIV diagnosis and clinic presentation in the RSA group was significantly lower than that of the historical control group (Table 2). This same truncation was seen in time from clinic presentation to ART initiation. Commensurate with the preceding, time from diagnosis to ART initiations was significantly shorter in the study RSA group than in the non-RSA control group. In the study RSA group, 33 (76%) participants initiated ART within 3 days of their diagnosis.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Study RSA n = 45</th>
<th>Non-RSA Control n = 42</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis to clinic presentation</td>
<td>0.0 (0.0–3.0) days</td>
<td>10.0 (5.0–34.75) days</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Clinic presentation to ART</td>
<td>0.0 (0.0–0.0) days</td>
<td>42.0 (28.25–64.75) days</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Diagnosis to ART initiation</td>
<td>0.0 (0.0–3.0) days</td>
<td>53.0 (42.25–95.25) days</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

All study RSA participants were on B/F/TAF for the entirety of their time on study. The non-RSA historical control patients were on a variety of regimens, with the largest proportion (45.2%) being on a single tablet regimen of elvitegravir, cobicistat, emtricitabine, and tenofovir (TDF or TAF; Appendix B).

**Virologic Outcomes**

There were no virologic failures noted through 48 weeks for those on B/F/TAF. Genotype testing was successfully completed for 39 (86.6%) participants during their time on study. The median time from diagnosis to receiving genotype laboratory results was 23 days (IQR 20–31 days). Among the 39 patients, transmitted drug resistance mutations were present in 10 (25.6%), with a major NNRTI mutation present in 8 (20.5%). No participants had transmitted INSTI resistance. One participant had genotype results showing a resistance mutation (M184V) against emtricitabine after reaching viral suppression on B/F/TAF. No participants switched regimens due to genotype results. Two participants voluntarily changed regimens after reaching viral suppression, one for gastrointestinal side effects and the other because of a preference for a long-acting injectable.
Forty-three (95.6%) study participants had a documented viral load of < 200 copies/mL by week 48. The remaining 2 participants had an unknown viral load because of patient refusal of laboratory tests. Forty-one (91.1%) reached < 50 copies/mL while on study; the additional 2 participants who did not reach < 50 copies/mL ended study participation less than 3 months after diagnosis.

We compared the viral suppression outcomes of a historical non-RSA population (n = 42) to those of our study population. We found the durations from HIV diagnosis to viral suppression < 200 copies/mL and < 50 copies/mL were shorter in RSA patients than in non-RSA patients (p < 0.001; Table 3).

Furthermore, the times from ART initiation to viral suppression to < 200 copies/mL and to < 50 copies/mL were shorter in RSA patients than in non-RSA patients (p < 0.001). In the study group, 36 (80.0%) participants achieved virologic suppression in 30 days or less from ART initiation. All participants who achieved virologic suppression while on study did so in less than 6 months (maximum 163 days) from ART initiation.

Table 3
Time to Virologic Suppression in Study RSA and historical Non-RSA Control

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Study RSA</th>
<th>Non-RSA Control</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis to viral load &lt; 200 copies/mL, median (IQR)</td>
<td>21.0 (11.0–31.0) days</td>
<td>112 (81.5–196.0) days</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>ART to viral load &lt; 200 copies/mL, median (IQR)</td>
<td>16.0 (9.0–29.0) days</td>
<td>34.5 (30.25–73.50) days</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Diagnosis to viral load &lt; 50 copies/mL, median (IQR)</td>
<td>32.0 (19.0–56.0) days*</td>
<td>181.0 (110.5–279.8) days</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>ART to viral load &lt; 50 copies/mL, median (IQR)</td>
<td>28.0 (13.0–56.0) days*</td>
<td>62.0 (34.0–173.5) days</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

*n = 41

Retention in Care and Treatment Adherence

Twenty-nine (64.4%) participants were still engaged in study at 48 weeks. Nine participants left the study before 48 weeks because they transferred care (7) or changed regimens (2). Seven (15.5%) participants were considered lost to care at 48 weeks because they did not present for the final study visit. The median treatment adherence was 93.4% (interquartile range 76.5% – 99.4%), based on pharmacy dispense data.

Patient Acceptance of RSA

All enrolled participants started ART the same day as their first appointment. Twenty-seven participants completed the end of study questionnaire. Participant responses regarding how they felt starting ART immediately after their diagnosis were reviewed and several common themes were identified. The first
and most common theme was general positivity, defined by feeling happy, good, supported, or relieved at starting ART. The second theme was an expressed readiness to start or not wanting to “waste time” before starting medication. The third theme was a sense of responsibility, which was often defined by the participant feeling ART initiation was the right thing to do for their health. Lastly, some participants expressed being overwhelmed by the diagnosis, but trusted the provider’s advice to start medication.

When asked how we could improve the rapid start process, the majority (21) of participants had no suggestions. Three participants suggested we have fewer team members at the first appointment.

**Real-World Considerations**

Of the 27 participants who completed the end of study questionnaire, 17 (62.9%) identified at least one barrier to care they experienced over the course of the study. The median number of barriers identified was 2 per participant. The most common barrier to care was lack of stable transportation (Table 4).

<table>
<thead>
<tr>
<th>Barrier to Care Identified</th>
<th>Study RSA Completed Questionnaire, n = 27</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unreliable source of transportation, n (%)</td>
<td>11 (40.7%)</td>
</tr>
<tr>
<td>Unstable housing, n (%)</td>
<td>10 (37.0%)</td>
</tr>
<tr>
<td>Food insecurity, n (%)</td>
<td>7 (25.9%)</td>
</tr>
<tr>
<td>Lack of insurance or underinsurance, n (%)</td>
<td>6 (22.2%)</td>
</tr>
<tr>
<td>Behavioral health concerns, n (%)</td>
<td>5 (18.5%)</td>
</tr>
<tr>
<td>Substance use, n (%)</td>
<td>5 (18.5%)</td>
</tr>
</tbody>
</table>

In March 2020, the COVID-19 pandemic significantly changed operations at the clinical site. The study protocol was amended to allow for virtual visits and delayed laboratory results. Study appointments transitioned from clinic visits to a majority telemedicine appointments, and participants without phones were given a phone through our Care Management program to complete their appointments. Participants were initially encouraged to delay completing bloodwork due to risk of exposure to COVID-19, but were able to complete STI testing via at home test kits that included self-swabs and a prepaid return envelope. Trillium provided free pharmacy delivery to the patients’ homes or location of their choosing. Patients who were homeless or unstably housed could pick up their medication “curbside,” with no direct contact.

**Discussion**

This study shows that RSA is an effective model of care in a community health center setting and supports its role in ending the HIV epidemic. A daily single tablet regimen of B/F/TAF was effective for 95.6% participants to reach undetectable viral load in less than 6 months of ART initiation, despite variation in regimen adherence. Consistent with the literature\(^3\) – \(^12\), our study demonstrates that RSA
shortens the amount of time from an initial HIV diagnosis to the ART initiation, consequently shortening the time from diagnosis to viral suppression. More rapid and sustained virologic suppression decreases opportunity for transmission. Some previous studies have not seen significant changes in time from ART initiation to viral suppression\textsuperscript{8,11}; however, our study did show a shorter time from ART initiation to viral suppression.

The success of any treatment model depends on patients’ acceptance. Participants in this study were very agreeable to RSA. All study participants offered ART at their first visit accepted it. The standard questionnaire given at study completion showed participants were comfortable with the RSA process. Demonstrating patient acceptance in the diverse population from a community health center is important to getting other community providers to feel comfortable offering RSA to their patients.

Over the course of the study, we noted fourteen false reactive rapid point-of-care tests. Further analysis showed that these false reactive tests account for less than 0.2% of the tests performed at Trillium during the study time frame, which is within the published specificity rate\textsuperscript{22}. Since the testing specialists are most often the patients’ first point of contact, it is important they are proficient in their testing role and promote confidence in the care team.

As a multidisciplinary community health center, Trillium was well positioned to take on this pilot study given its 30-year legacy in HIV prevention and treatment, and long-standing culture of early HIV intervention. Experience combined with evaluation of our programs supports our ability to navigate changing healthcare landscapes. In the wake of the COVID-19 crisis, Trillium had to create and implement new ways to care for PLWH. Though challenging, care was minimally interrupted, and study participants who were virally suppressed before the pandemic remained suppressed throughout. However, in various clinical settings, implementation and maintenance of RSA can present challenges. Provider availability can make it difficult to accommodate a new patient appointment on the same day. On-demand insurance navigation and enrollment services are necessary to provide HIV treatment drug at little to no cost for patients, which may not be available in all states. RSA requires the mobilization and unity of individuals from across the care continuum, regardless of clinic size.

Our study has several limitations. The study was designed before RSA was included and defined as initiating ART within 72 hours of diagnosis in the New York State clinical guidelines\textsuperscript{23}. Though our definition of RSA differs from current guidelines, the median and interquartile range of time from diagnosis to ART initiation in the study population mirrors the 72-hour window (Table 2). The majority (33, 76%) of participants met the 72-hour definition of RSA, and an additional 8 participants initiated therapy between 3 and 7 days from diagnosis. Although the study population was controlled for ART regimen variations by using only single tablet regimen B/F/TAF, the historical control groups did not include this regimen because it was not yet approved by the FDA. For this reason, we are unable to identify whether the improved outcomes were more related to our RSA model versus the use of B/F/TAF. We are also unable to identify the specific elements of our RSA approach that influenced patients’ experiences the most.
As a pilot study, our study population size was limited. Future studies should include larger populations with longer follow-up periods. The control group was identified retrospectively, creating a potential for inadvertently leaving out some patients who presented with new HIV infections. The measure of treatment adherence used reflects the most adherent a patient could be given the amount of medication they have, which may not reflect the actual patient adherence. We attempted but were unable to complete accurate pill counts or obtain accurate reports of doses missed because participants frequently forgot to bring remaining medication with them to appointments.

**Conclusion**

RSA is becoming the standard of care for HIV treatment globally\textsuperscript{23,24}. Our study shows that RSA can be successfully implemented in a real-world community health center. RSA shortens the time to undetectable viral load and fosters engagement in HIV care. The single tablet regimen of B/F/TAF for RSA is well accepted by patients and effective at suppressing HIV-1 viral load to undetectable levels. Efforts to end the HIV epidemic leverage treatment as prevention, and RSA expedites the process by getting PLWH on ART and virologically suppressed faster. More rapid virologic suppression means less time for transmission to occur, leading to fewer new infections. RSA is an important tool for ending the HIV epidemic and real-world data from our study supports implementation in real-world community health centers.

**Abbreviations**
Declarations

This study protocol and informed consent forms were reviewed and approved by WCG IRB (Puyallup, WA). All participants provided written informed consent at their first visit before being enrolled on study.

Consent for publication not applicable.

Data Availability

The datasets generated and analyzed during this study are not publicly available due to patient privacy and the sensitive nature of data related to HIV status. De-identified or limited data sets are available from
the corresponding author (shilliard@trilliumhealth.org) on reasonable request.

Funding

Gilead Sciences, Inc. provided funding to assist with this collaborative research (CO-US-380-4644). The primary and sub investigators developed the study design and protocol independently.

Competing Interests

During the study, author M.M. was on the speaker bureau for ViiV Healthcare and author W.V. was a speaker for Gilead Sciences. Author R.C. was a medical scientist who represented Gilead in this collaborative study. Authors J.S., A.Z., and M.M. were affiliated with Trillium Health at study initiation and during data collection. Author J.S. is currently affiliated with CHEMED, 1771 Madison Ave, Lakewood, NJ 08701. Author A.Z. is currently affiliated with US Medical Affairs, Merck Research Laboratories, Kenilworth, NJ 07033, United States. Author M.M. is currently affiliated with Rochester Regional Health, Rochester, NY, United States.

Author Contributions

Authors W.V., J.S., M.M., A.Z., A.D., and R.C. made substantial contributions to the conception and design of the study. Authors W.V., J.S., M.M., A.Z., A.D., and S.H. made substantial contributions in the acquisition, analysis, and interpretation of data. All authors participated in revisions, read, and approved the final manuscript.

Acknowledgments

Thank you to Grace Jividen, Rose Matias, Russ James, Michael Lecker, PhD, MA, Madison Baker, and Nicole Kase for their invaluable contributions in data collection and study planning. Thank you most to our amazing patients who shared their journeys to further the science of HIV treatment.

References


Figures
Figure 1

Screening, Enrollment, and Retention Flowchart

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendices.docx