John Chalker

Improving ART adherence at reproductive and child health clinics integrating Option B+ in Tanzania

July 2017

Impact Evaluation Report 59

HIV and AIDS

3ie International Initiative for Impact Evaluation

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About this report

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Management Sciences for Health

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Summary

In previous work in antiretroviral therapy (ART) clinics, Ross-Degnan and others have shown that the rate of a patient attending appointments on time in a particular facility correlates with their rate of medication adherence and clinical outcome (2010). ART clinics in three East African countries found that implementing a minimally invasive, low-cost patient appointment and tracking system allowed ART staff to identify missing patients promptly, facilitate the management of their workload and promote sustainable and consistent clinic attendance by HIV-positive patients (Nyamusore et al. 2011; Mwatawala et al. 2012; Boruett et al. 2013).

In June 2013, Tanzania adopted Option B+, whereby all HIV-positive pregnant women receive all ART at reproductive and child health (RCH) clinics, rather than the specialized ART clinics, which had previously been the sole providers of ART. The Prevention of Mother-to-Child Transmission Unit of the Ministry of Health and Social Welfare distributed the appointment and patient tracking registers to all RCH Option B+ clinics but gave no formal orientation for their use. The Ministry of Health and Social Welfare reported that adherence and retention to treatment were problems.

For this research, our goal was to conduct a cluster randomized controlled trial to evaluate whether orienting Option B+ RCH clinic staff on the use of the appointment and patient-tracking registers improves appointment attendance rates in these newly integrated facilities.

Methods

We implemented a matched pair randomized controlled trial in 24 RCH facilities in 8 matched districts in Mbeya region in Tanzania. The intervention included training for two staff members from each facility to orientate them on how to use the appointment tracking system and conducting four rounds of supportive supervision at each intervention clinic at monthly intervals to reinforce the training.

At baseline, we collected data on established patients: women who initiated ART at least five months prior to initial data collection and had attended the clinic within the previous three months. The evaluation team collected data from pharmacy and clinic records. At the final data collection (five months after the final supervisory visit), we followed as many of the baseline patients as possible. In addition, we included an additional group of women who had recently initiated treatment in the 6–12 months prior to the intervention and the 6 months after the intervention, for whom we collected visit data for up to 6 months post-initiation.

We also collected qualitative data through interviews at baseline in intervention districts with clinic staff members, district staff members and women on ART at each clinic. For the endline study, we interviewed clinic staff members, district staff members and women on ART at both intervention and control facilities.

We used three rigorous statistical approaches to evaluate program effects: interrupted time series with comparison series analysis, generalized estimating equation difference-in-difference estimation, and Kaplan-Meier survival curves with accelerated Cox failure

time models. Models were adjusted for possible pre-post changes in outcomes in the control group and all models controlled for clustering.

Results

At baseline, 37–39% of appointments were not attended on time. The baseline level and trend of visits missed by more than 1, 3, 7 or 15 days were graphically similar, with negligible statistical differences in the intervention and control groups. Six months after the intervention, the rate of missed visits in the intervention group was more than 13 percentage points lower (confidence interval [CI]: -0.154 to -0.121). However, the relative difference between rates of patients lost to follow-up, as measured by missing visits by more than 60 days, was minimal. There was also a significant increase of 7.3 percentage points in patients attaining 95 percent or better coverage with dispensed medicines relative to controls. At endline, facilities gave ART adherence a high priority with assistance from outreach programs. Improvements in the health system as a result of the intervention, reported by both clinic and district staff and women on ART, were timeliness of care, treatment confidentiality, patient–provider interaction and reduced workload.

The cost of this intervention worked out at about 1 extra woman achieving 95 percent of days covered by dispensed medicine per 1 training-level cadre person-day and 1 facility staff person-day. However, if this were scaled up, the expense would be minimal because the work would be absorbed into routine practices.

Conclusions

The manual system of appointment tracking, and subsequent community outreach for patients who miss appointments, was relatively simple to implement with two days of training and subsequent supervisory visits. The intervention significantly improved appointment keeping and consistent availability of antiretroviral medicines for patients in the intervention group compared with the control group for patients on long-term ART. The facility staff were better able to control their workload, quickly identify missing patients, work with existing community organizations and bring back missing patients into care.

At the same time, patients noted that they were able to choose convenient days for their appointments and wasted less time waiting for treatment in the clinic. There is now enough evidence to scale this up to all ART and Option B+ RCH clinics in Tanzania, as well as to try such an intervention in general medical clinics treating other chronic conditions.

Contents

List of figures and tables

Acronyms and abbreviations

ART	Antiretroviral therapy
ARVs	Antiretrovirals
CD4	Cluster of differentiation 4
CI	Confidence interval
CTC	Care and treatment clinic (HIV and AIDS)
DiD	Difference in difference
GEE	Generalized estimating equations
ID	Identification
INRUD IAA	International Network for the Rational Use of Drugs Initiative on Antiretroviral Adherence
ITS	Interrupted time series
MOHSW	Ministry of Health and Social Welfare
MSH	Management Sciences for Health
OR	Odds ratio
PDC	Percentage of days covered (by dispensed medicine)
PMTCT	Prevention of mother-to-child transmission (of HIV)
RCH	Reproductive and child health
WHO	World Health Organization

1. Introduction

Until recently, all antiretroviral therapy (ART) for HIV and AIDS was administered through specialized clinics. In the middle of 2013, Tanzania officially adopted Option B+ for pregnant women in all of their reproductive and child health (RCH) clinics. Under Option B+, HIV-positive women now receive lifelong ART regardless of their cluster of differentiation 4 (CD4) count. For the first time, ART was being administered outside of specialized HIV clinics.

The RCH clinics provide ART to women under Option B+ both prenatally and for two years postnatally. This innovation means that the RCH clinics have had to integrate HIV and AIDS care into their routines. However, the Ministry of Health and Social Welfare (MOHSW) reported that adherence to and retention in treatment were a problem under the program. Good adherence to ART is essential if it is to be successful and if developing resistance to the medicines is to be avoided.

In our previous work in ART clinics, we have shown that the rate of patients attending appointments on time in a particular facility correlates with medication adherence and clinical outcome (Ross-Degnan et al. 2010). But until recently, very few ART clinics in Tanzania could identify who they were expecting on a given day or could rapidly identify patients who had not arrived when expected, because they lacked efficient appointment systems (Chalker et al. 2008). By the time patients were identified as lost to follow-up, they may have already missed several months of treatment with a greatly enhanced risk of developed resistance and treatment failure. This same problem now exists in the RCH clinics.

ART clinics in three East African countries found that implementing a minimally invasive, low-cost patient appointment and tracking system allowed them to promptly identify missing patients, facilitate the management of their workload and promote sustainable and consistent clinic attendance by HIV-positive patients (Nyamusore et al. 2011; Mwatawala et al. 2012; Boruett et al. 2013). The Prevention of Mother-to-Child Transmission (PMTCT) Unit of the RCH Section of the MOHSW distributed the appointment books and systems that were developed in our previous work to all RCH clinics, but none of the RCH clinic staff understood how to use them.

Our goal was to orientate staff on the use of the appointment and patient tracking system in Option B+ RCH clinics, empowering staff to:

- plan their work schedules
- control their workload
- rapidly identify patients who had missed appointments
- develop ways to follow up on patients who have missed appointments
- produce and discuss monthly appointment-keeping indicator values.

The primary hypothesis was that by orienting the RCH clinic staff to be able to use the appointment system, consistent clinic attendance by HIV-positive patients would improve.

If we could show that orienting the RCH clinics to use the appointment system, as well as supervising clinic staff in the early stages of implementation, improved retention and

adherence, then we believed that the MOHSW would be interested in establishing the system as a national best practice.

1.1 Broad objective

Our broad objective was to develop an intervention strategy based on the introduction of an appointment-keeping and patient-tracking system and measure its effects in improving adherence to ART in RCH clinics operating Option B+ in Tanzania.

1.2 Specific objectives

We had specific objectives:

- Establish baseline measures for rates of adherence measured through indicators:
  - percentage of clinic appointments attended on or before the day scheduled (primary outcome)
  - percentage of clinic appointments attended on or before or within three days of scheduled date
  - percentage of clinic appointments attended on or before or within seven days of scheduled date
  - percentage of days covered by dispensed antiretrovirals (ARVs)
  - time until a gap in clinic attendance of 15 or more days
  - time until loss to follow-up (defined as no clinic contact for 60 days from missed appointment)
- Evaluate the effectiveness of restructuring the appointment system to make the date negotiable and the appointment for a specific period of the day in increasing attendance on the day of the appointment and in reducing patient waiting time.
- Evaluate the effectiveness of strengthening the patient-tracking system in improving the identification of patients who have not attended and speeding up their return to the clinic.

2. Background

2.1 Situation in Tanzania

To roll out the new Option B+ program rapidly, the plan was to implement it in all 4,914 RCH clinics by June 2014. By December 2013, more than 10,000 mothers were on ART, and by June 2014, almost three-quarters of the clinics had implemented Option B+. However, the RCH Section's PMTCT Unit was finding it a challenge to ensure high rates of clinic attendance, medication adherence and retaining patients in care.

The PMTCT Unit compiled numbers of women by region who were HIV positive and on ART as of July 2014. Unit staff saw Mbeya as a priority region, as it had the most women initiated on ART, as is shown in Table 1 below.

Table 1: HIV-positive women on ART by region: July 2014

Region	Total women tested HIV positive	HIV-positive women initated on ART
Dar Es Salaam region	30,020	0
Mbeya region	12,247	4,880
Tabora region	7,817	864
Morogoro region	6,579	307
Mara region	5,823	209
Pwani region	4,983	469
Mwanza region	4,821	2,091
Iringa region	4,486	892
Shinyanga region	4,418	1,406
Kagera region	4,402	1,782

Almost all regions of Tanzania have development partners on the ground to help the MOHSW improve AIDS and RCH care. Typically, their projects support the strengthening of the health system in that region. In Mbeya, this organization is the Walter Reed Program. We planned this intervention to align with their existing programs.

The Walter Reed Program was developed with local partners in the Southern Highlands, including Mbeya region, and is carried out in collaboration with the Mbeya Referral Hospital and the Mbeya Regional Medical Office in coordination with the MOHSW and the National AIDS Control Program. Of particular interest to this program were the linkages that the program had developed with local non-governmental organizations, allowing patients to receive support at the community level.

2.2 Intervention

We conducted two trainings. The first was to create a team of trainers that could train staff in the health facilities' RCH/PMTCT units and supervise staff in the Option B+ clinics. The second and primary training was to train the Option B+ clinic staff in the skills and systems needed to be able to quickly identify clients missing their clinic appointments and to initiate early follow-up procedures. The training was followed by a series of four supportive supervision visits at monthly intervals to each intervention clinic.

2.2.1 Training of trainers

Management Sciences for Health (MSH) and the PMTCT Unit organized a two-day training of trainers for PMTCT and MSH staff members and two recruited trainers. The training focused on the results of the baseline assessment and how the appointment and patient-tracking registers can improve adherence to ART. Participants had a practicum to understand how to fill out the registers correctly and how to use the information to track clients that missed appointments. Participants then provided all direct training to the intervention facility staff.

2.2.2 Training of RCH staff providing Option B+ services

Staff trained came from 12 intervention health facilities. Participants included two staff members working at the Option B+ clinic, and one staff member from the ART clinic from

each facility. All Option B+ clinic staff were diploma-level nurses. RCH coordinators from the intervention district councils, together with those in charge of RCH clinics, also attended.

Trainees were divided into two groups so that the facilities would not have so many staff absent at one time. We trained each group for two consecutive days using interactive learning methods. The training agenda was divided into four activities.

Activity 1 involved discussing issues of adherence and retention, based on the findings of the baseline survey (described in the evaluation section).

Activity 2 was the presentation of the appointment system. Where the clinics were using paper-based systems, the team introduced a standardized paper-based appointment register that enabled staff to monitor appointment keeping effectively.

During activity 3, we discussed local resources to trace missing patients and helped the clinic staff to either introduce or strengthen a system to track patients who have missed their appointments. Staff used the new appointment register to identify patients rapidly who miss appointments and then transfer their information to the new tracking register.

In many districts, community organizations can help to follow up on missing patients if the clinic knows who was missing and has a relationship with the organization. Other patients who live nearby can also be recruited to visit the missing patient, or someone can contact the person by mobile phone. The staff members at each facility determined which option was the most feasible for their clinic and for particular patients. After discussion, the final step of activity 3 was the creation of a feedback system, so that the facility staff could find out why a patient had missed a visit.

In activity 4, the team taught the staff how to calculate the monthly appointment-keeping indicator from the appointment system data to monitor their progress. The indicator for appointment keeping is the percentage of patients who arrived for their appointment on or before or within three days of the scheduled day. By assessing this each month, the clinic staff can monitor their performance and discuss the results and possible actions at monthly staff meetings, which is an important mechanism for instituting a culture of continuous quality improvement.

2.2.3 Supervision visits

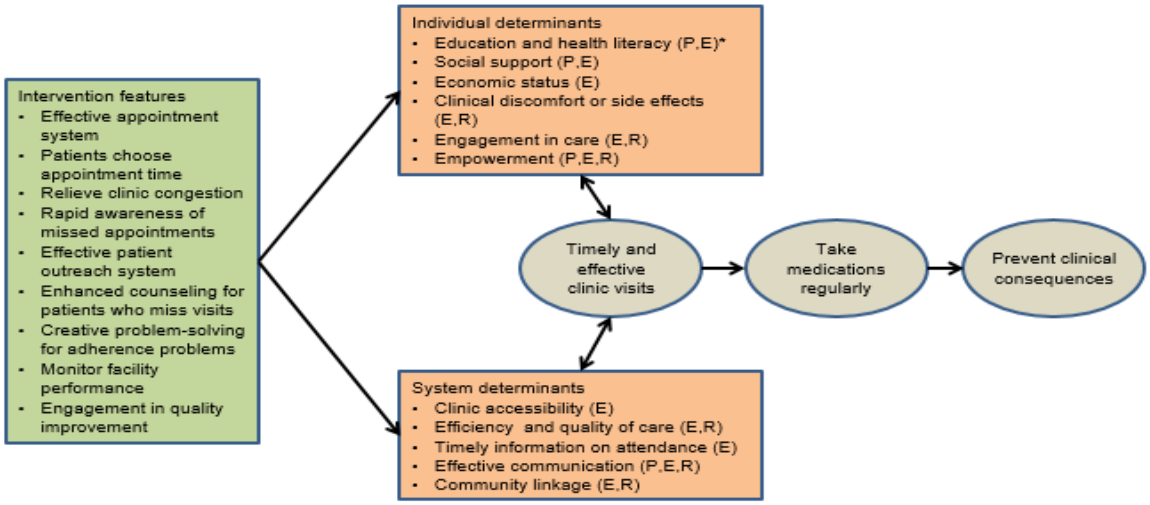
We scheduled a series of four supportive supervision visits after training to ensure that staff members understood and implemented the processes for: (1) scheduling appointments; (2) recording when patients actually attend the clinic; (3) having a system for rapidly following up on patients more than three days late for their appointment; and (4) knowing how to calculate the monthly attendance indicators to track their progress. Supervision also addressed clinic staff's problems with introducing the systems.

The goal of the intervention and the four follow-up supervisory visits was to empower the facility staff to use the appointment and patient-tracking tools. Once they have established these practices, they can monitor the clinic's performance and discuss ways to improve. Each clinic developed its own mechanisms to encourage mothers to attend the clinic on their scheduled days.

2.3 Theory of change

In our previous work in the International Network for the Rational Use of Drugs Initiative on Antiretroviral Adherence (INRUD-IAA), we used both quantitative and qualitative methods to explore the prevalence and determinants of adherence and appointment keeping in five East African countries (Gusdal et al. 2009; 2011; Chalker et al. 2010; Ross-Degnan et al. 2010). We showed that both individual-level and system-level barriers can affect appointment keeping and adherence to medications in East Africa, and this ultimately compromises optimal clinical outcomes (Gusdal et al. 2009). For practical reasons, INRUD-IAA focused on developing affordable system-level interventions that target both systems-related and individual barriers to adherence (see Figure 1). What emerged was the establishment of practical appointment systems for scheduling patients, tracking attendance and monitoring overall performance over time, as well as community outreach to reconnect with patients who miss appointments.

Figure 1: Intervention features addressing individual- and system-level determinants of adherence



* P=predisposing, E=enabling, R=reinforcing determinants of adherents identified in INRUD-IAA

Our theory of change is that a functioning appointment and patient tracking system will enable patients to attend on time by scheduling their visits within a preferred date and time window. Patient scheduling decongests clinics and allows more time for staff to counsel and reinforce adherence messages. The development of this theory of change was informed by the theoretical constructs of Green's PRECEDE-PROCEED planning model (Green and Kreuter 2005). The model's key construct is that health behaviors are influenced by predisposing, enabling and reinforcing factors that operate at both the individual and environmental level. The goals of applying this model to a given problem are to first understand the relevant behaviors and environments, and then to design and evaluate interventions that can influence the behaviors themselves, the settings that influence them, and their health consequences. Therefore, the PRECEDE-PROCEED process involves a diagnostic phase of exploring the predisposing, enabling and reinforcing factors that influence the target health behavior in a given setting, then developing, implementing, and evaluating an intervention that has the potential to address them.

Establishing an appointment system and identifying and using local resources, such as community outreach systems, to help patients attend on time can reduce both system-level and individual-level barriers, such as excessive waiting times. This is reinforced by regularly monitoring and discussing facility performance based on the appointment-keeping indicator. These interventions build clinic staff commitment to focusing on attendance and encourage creative solutions to sustaining patients on therapy. The intervention was designed to increase: (1) patient engagement, by including patients in decision-making on their appointment schedule rather than demanding their presence on certain days (Gusdal et al. 2009); (2) patient–staff communication because poor communication has been shown to discourage attendance (Gusdal et al. 2009); (3) linkage to community support systems to encourage attendance and bring people back into care (Mwatawala et al. 2012); and (4) a facility focus on improving quality of care (Nyamusore et al. 2011; Mwatawala et al. 2012; Boruett et al. 2013).

We expected that the intervention approach tested in INRUD-IAA in ART clinics would be even more effective in the new context of RCH clinics, where HIV-positive women identified by prenatal screening are treated preventively. We believed that pregnant women would be motivated to achieve the best outcomes for their children, which requires their own good health. Also, they have received counseling on the need for maintaining ART for life. Similarly, RCH staff wish to contribute to the best outcomes for mothers and children and already have a culture of monitoring pregnancy-related indicators.

2.4 Implementation

Implementation broadly went as planned apart from some delays. This meant that, overall, by the end of the project we were 12 weeks behind the original proposal. Ethical clearance was received 23 April 2015. Baseline data were collected April 27–May 18. Training of regional teams took place in May 2015 and for clinic team in July, with the first supervisory visit taking place in August. Full implementation of the appointment book intervention occurred sometime between the second supervisory visit and the fourth supervisory visit in November 2015. The endline assessment took place in April 2016.

2.4.1 Uptake

By the end of the four supervision visits, the supervision team thought that all clinics were managing the appointment register and missed appointment-tracking register. However, implementation was not immediate, but showed continuous improvement over each of the supervision visits. Individual clinic progress can be seen in Table 2.

The first supervision visit to the Mbeya Regional Referral Hospital found that staff at the Option B+ clinic were different than those who attended the training, so that the first supervision visit became another basic training for the group of four nurses who staffed the clinic. There was no measurable difference in training in this way. The staff continued to face challenges because of the large number of clients that they saw during their 1 scheduled day of Option B+ appointments; however, by the fourth supervision visit, staff were taking measures to increase the number of clinic days from 1 to 3 a week and were keeping the registers properly updated.

Only five clinics implemented the time block system for making appointments. The other clinics thought that all their patients would want to come in the morning.

By the fourth round of supervision, feedback from clinic staff was that they felt that they knew how many clients to expect in a day and were able to distribute their clients across the month to even out the workload, resulting in fewer clients waiting. They could recognize who did not come on their scheduled day and had discussed the best ways to improve their clients' appointment keeping and to trace missing patients. The community groups who provide support in following up with clients had learned how to use the register to facilitate their work.

Table 2: Facility progress over the course of the four supervision visits

			By which of the 4 supervision visits was the following seen to be working well			
District	**Facility #**	Approx. # clients	Block system	Using appt register correctly	Using client tracing register correctly	Using and discussing monthly indicators
Mbeya City	1	550		3rd	2nd	2nd
Mbeya City	2	360	4th	4th	4th	2nd
Mbeya City	3	180		3rd		3rd
Mbeya City	4	500		4th		4th
Mbeya City	5	470		3rd	4th	2nd
Chunya District	6	190		2nd	3rd	2nd
Chunya District	7	386	4th	3rd	4th	3rd
Kyela	8	220		3rd	1st	2nd
Kyela	9	360		4th	1st	2nd
Mbozi	10	90	1st	4th	1st	2nd
Mbozi	11	210	3rd	3rd	3rd	2nd
Mbozi	12	290	3rd	3rd	1st	2nd

2.5 Primary outcomes of interest

The primary question addressed in this impact evaluation was whether the introduction of an appointment system in RCH clinics in Tanzania with community follow-up of non-attenders improves adherence to appointment keeping and continuity of ART for HIV-positive women.

Study outcomes include:

- percentage of clinic appointments attended on or before the day scheduled (primary outcome)
- percentage of clinic appointments attended on or before or within three days of scheduled date
- percentage of clinic appointments attended on or before or within seven days of scheduled date
- percentage of days covered by dispensed ARVs
- time until a gap in clinic attendance of 15 or more days
- time until loss to follow-up (defined as no clinic contact for 60 days from missed appointment).

As mentioned, we have shown that these measures can be collected reliably in health facilities in East Africa using routine data and that they predict clinical outcomes (Chalker et al. 2010; Ross-Degnan et al. 2010).

3. Data and methods

3.1 Ethical approval

We developed quantitative data collection tools as part of the proposal and submitted it to Tanzania's National Institute for Medical Research for ethical clearance. We drafted an information sheet about the study in Swahili and obtained written consent from all respondents. Confidentiality of all study participants was assured. MSH informed the responsible district authorities before the study to ensure support and assistance, if needed. The National Institute for Medical Research approved the study on April 23, 2015.

3.2 Quantitative data collected

3.2.1 Statistical approach and power calculations

Our primary outcome in this study is missed clinic visits on the scheduled day, as measured from data in clinical records. We used aggregate and individual-level interrupted time series (ITS) models to compare changes in the rate of missed visits in the intervention versus control clinics pre- and post-implementation of the appointment-keeping and patient-tracking intervention.

We used PASS software, with both 0.001 and 0.01 as estimated values of the intraclass correlation coefficient, to calculate power, with the higher value resulting in lower power. Typical values for estimating the intraclass correlation coefficient range from 0.002 to 0.05 (a wide range). Since missed visits are due to individual as well as system-level issues, we expect relatively low correlations between individuals within each cluster; thus, we used the smaller range of 0.001 to 0.01. The overall rate of missing clinic appointments typical in HIV and AIDS clinics in the baseline period of our previous study was approximately 30 percent. In this context, with 12 health facilities per study group, an average of 100 patients per facility per month, and an expected 12 months before and 9 months after the intervention, we expected 80% power to detect changes in rate of missed visits of 4.6% to 6.0%, assuming 0.001 and 0.01, respectively (Donner and Klar 2000; Zhang et al. 2011).

3.2.2 Study population and sampling

We purposively selected Mbeya region, which the MOHSW identified as a priority region because of its high prevalence of HIV-positive pregnant women (13%). Because it would increase the possibility of contamination to have intervention and control facilities within the same districts, we purposively selected all clinics with 70 or more women on ART in Option B+ clinics, and then paired districts in the region by the numbers of these selected facilities. Two districts had 5 qualifying clinics, each with more than 70 registered patients, selected as 1 pair. One district (Mbozi DC) had four such clinics and one had three (Momba). One clinic was randomly dismissed from Mbozi to make another district pair. The other 4 districts with qualifying clinics all had 2 qualifying clinics each, except Chunya, which had 3. One was randomly deselected from Chunya to make two

pairs of districts with two clinics each. We randomly assigned one of each pair of districts to intervention and control groups, ending with 12 health facilities in 4 districts in the intervention group and 12 facilities in 4 separate districts in the control group (Table 3).

According to the information provided by the PMTCT Unit, the expected average number of women on ART would be 147 per facility.

Table 3: Pairing of districts based on number of facilities and number of women on ART based on MOHSW records

Intervention

Pair	District	Facility #	Total women on ART	Max of 200 selected
1	Mbeya City Council	1	306	200
1	Mbeya City Council	2	267	200
1	Mbeya City Council	3	108	108
1	Mbeya City Council	4	265	200
1	Mbeya City Council	5	395	200
2	Chunya DC	6	175	175
2	Chunya DC	7	226	200
3	Kyela DC	8	121	121
3	Kyela DC	9	205	200
4	Mbozi DC	10	102	102
4	Mbozi DC	11	93	93
4	Mbozi DC	12	164	164
			2,427	1,963

Control

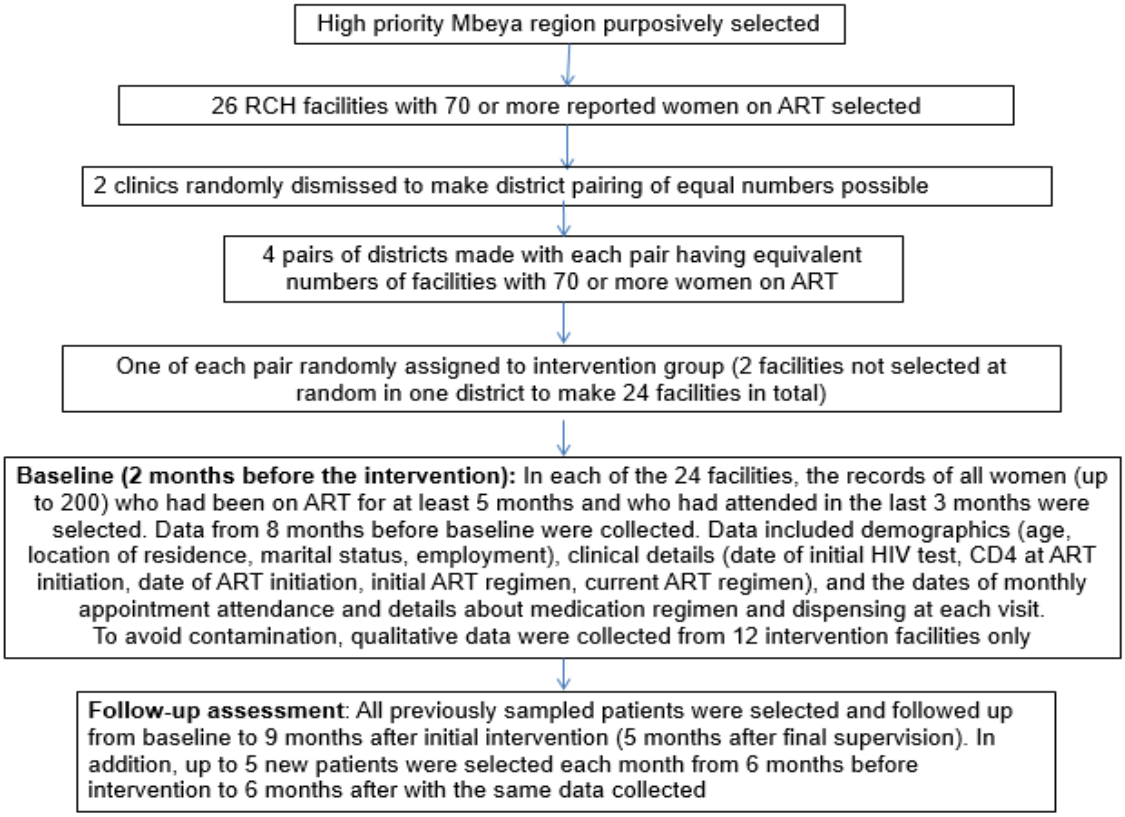
Pair				
1	Mbarali	13	191	191
1	Mbarali	14	382	200
1	Mbarali	15	82	82
1	Mbarali	16	109	109
1	Mbarali	17	86	86
4	Momba	18	86	86
4	Momba	19	256	200
4	Momba	22	196	196
3	Rungwe	20	122	122
3	Rungwe	21	98	98
2	Mbeya DC	23	101	101
2	Mbeya DC	24	103	103
			1,812	1,574

In May 2015, two months before the start of the intervention, we conducted a baseline assessment of clinic attendance and perceptions about barriers to continuity of care and used the findings during the intervention. During the assessment, the evaluation team visited each clinic and reviewed clinic and pharmacy records to extract data. They identified patients who had started ART at least 5 months prior to the assessment visit and who had at least 1 visit in the 3 months prior to the visit, that is, women who were experienced on ART and who were current patients in the facility shortly before the intervention. These are known as established ART patients.

We extracted data for these patients from June 2014 to April 2015 for the baseline assessment, and then followed them through the end of the study. This fixed cohort of established ART patients who were still attending shortly before the intervention is the primary cohort of interest for measuring study outcomes.

In considering the possible effects of the intervention, we decided during the study to also examine the effects of appointment systems on newly treated patients during their first six months of therapy. During the follow-up survey, conducted five months after the final supervisory visit, we therefore identified a secondary rolling cohort of newly treated patients. We limited inclusion in this rolling cohort to a maximum of five newly treated patients per month per facility. These were selected for those initiating treatment 6–12 months before the intervention and for 6 months after the intervention training, comprising a total of up to 60 newly treated patients per facility, or up to 360 per intervention and control group. Due to the relatively short follow-up period after the intervention, some of the newly treated cohorts were only followed for four or five months. The addition of the second cohort of newly treated patients and the analysis of time until study outcomes strengthened the overall evaluation. Figure 2 illustrates our sampling process.

Figure 2: Sampling process



3.2.3 Data collection methodology

We collected three types of quantitative data at health facilities during the baseline and follow-up assessments:

- facility data, including facility name and code, name and contacts of facility in charge and data contact person, date of data collection, and number of clients on ART;

- patient data, including name, patient number, age, date of birth, marital status, date of start of ART, World Health Organization (WHO) stage and CD4 count at start of ART; and
- visit data, including date, WHO stage and CD4 count on that day, ART regimen, days dispensed and next visit date.

All women on ART in the RCH facilities in the intervention districts received the intervention. Our analytic sample is taken from 12 months before the start of the intervention to 9 months after, and includes: a) all women (up to of 200 per facility) who were established on treatment for 5 or more months at baseline; and b) up to 5 newly treated patients per facility per month before and after the intervention (Table 5).

We captured data on all these women's visits to the sampled health facilities during the entire study observation period. Five of our outcomes (missed visits, visits missed by more than 3 days and 7 days, time until occurrence of a gap in clinic attendance of 15 or more days, and time until loss to follow-up) were derived from appointment dates recorded in pharmacy or medical records, particularly the care and treatment clinic (CTC) card known as the CTC 2 card. At each completed patient visit, clinics record the date of the next expected visit in the patient's record. If dates were missing, we based the expected visit date on the number of days of medication dispensed. The first two outcomes are specified as rates, while the second two are time intervals from the beginning of follow-up (in the baseline period) or the start of the appointment system (in the follow-up period) until the occurrence of the outcome.

The national-level data collection team comprised staff from MSH, the PMTCT Unit, and five other experienced staff from public health facilities, accompanied by a representative from the Mbeya Regional Medical Office and district RCH coordinators. The data collection team was split in two, with each team including four national-level staff working with district and regional staff.

Each data collector received a Samsung Galaxy tablet with an Open Data Kit application. They collected all data using the tablet and uploaded it daily to a web-based aggregator. For the variables and screen shots, see Appendix A.

3.2.4 Avoiding bias

We used a randomized matched pairs sampling strategy. Random allocation minimizes the likelihood of selection bias as well as most other threats to internal validity (Shadish et al. 2002; Rossi et al. 2004).

By assigning facilities to district pairs, we maximized geographic separation between facilities to minimize contamination. In addition, ITS with comparison series analyses of cluster randomized clinical trials has been shown to produce results that are generally equivalent to more typical difference-in-difference (DiD) analyses of randomized clinical trial designs (Fretheim et al. 2013; 2015). This type of longitudinal analysis has the additional advantage of being able to also adjust for differences in pre-intervention trends between groups, which are commonly observed in cluster randomized trials with relatively small numbers of clusters (Cook and Campbell 1979; Wagner et al. 2002).

Furthermore, ITS analysis can detect dynamic effects that increase or decrease over the course of the post-intervention period, which may occur during and after the period of post-intervention supervisory visits. Similarly, segmented survival models of time until gaps in clinical attendance and dropout can establish the equivalence of the baseline hazard functions in the intervention and control groups prior to the intervention and compare changes in hazard functions between groups post-intervention.

Our individual-level GEE and survival models use data on patient demographics and clinical characteristics to adjust for differences between intervention and control groups and to accommodate changes in the study population over time.

3.2.5 Data quality control measures

Repurposing routine data that is collected to document the process of care at health facilities for research is always challenging. In many settings, data recorded on medical records and pharmacy forms is missing or incorrectly recorded—this study was no exception. We originally expected that several additional fields from the standard CTC 2 treatment form used in all HIV treatment programs in Tanzania would be available in this study (e.g. self-reported adherence, reasons for non-adherence, CD4 counts, reported side effects, reasons for medication switching). However, following the baseline survey, we determined that information in these fields was unreliable and incomplete, so we did not collect it in the endline data collection. Fortunately, the fields that were most essential for measuring the outcomes in this study were the most complete: date of visit, date of next visit and amount of medication dispensed. Even when a record was missing this information, data collectors could work with local clinic staff to determine if they were standard across all patients (e.g. scheduled appointment in 28 days, 30 days of medication dispensed). If so, they documented this in their notes from the data collection process and it was taken into account to impute missing data.

This study used electronic tablets to collect data at health facilities. Use of electronic data capture allowed programmed restrictions that limited the number of wild codes that could be entered. Capturing data electronically also eliminated the need for post-survey data entry, which shortened the time needed to assemble a study dataset for analysis. Supervisors checked and resolved problems with data collectors each evening in the field after returning from health facilities. They transmitted data to a central server, and we carried out preliminary analysis of data quality during the first week of data collection in both the baseline and endline surveys. The design of the data collection application was substantially improved for the endline assessment to improve usability by data collectors, and it was simplified by the elimination of fields that were determined after the baseline assessment to be unreliable.

Studies using routine health facility data that depends on dates to measure outcomes or predictors invariably suffer from the vagaries of how this information is recorded in medical and pharmacy records. While the data collection application was able to screen for and prevent the entry of dates outside the study range, dates that were within the study range were entered as they were found in the record. This led to errors that routinely occur with this type of information, including incorrect years (especially at the beginning of a new year), transposed dates for the visit and next scheduled visit, the same date used for visit and scheduled date, reversal of the numbers for day and month in the early part of a month, and so forth. A major step in data cleaning was identifying

and correcting errors that could be corrected logically. We eliminated data on a small number of visits where the dates simply did not make sense, causing a slight overestimation in the rate of missed visits from 1 to 15 days. These errors were not differential by study group.

In this early period of implementation of the Option B+ program in RCH clinics, insufficient attention was paid to the consistency and quality of record keeping. Staff in these clinics are familiar with records for maternal healthcare, but the information requirements of an ART program are new and different for them. This meant a sparser array of reliable covariates for this study. For the long-term success of the Option B+ program, greater attention must be paid to training staff about the need for and process of reliably collecting and recording data that is essential for HIV treatment and long-term patient management.

3.2.6 Problems and challenges

Early implementation went less smoothly than planned. While facility staff were able to learn to use the appointment book after the initial training and understood the need for ongoing outreach systems for patients who missed appointments, several sites were slow to take up the appointment and outreach systems as routine processes, until after the first and even the second round of supervisory visits. Because changes in routine clinic processes are challenging to implement, we had anticipated the need for active supervision, especially during the early months. The future success of these systems in Option B+ clinics will depend on the timing and quality of these supervisory visits.

The field teams also faced several challenges during the data collection, and the study benefited from the team supervisors' strong leadership and flexibility:

- Travel logistics took much time. This included reporting to the district headquarters and traveling to reach the facilities. This was particularly true during the endline data collection during the rainy season, where many roads were difficult to pass;
- Reporting to the head of the facility, getting staff assigned to work with the teams, retrieving the files and finding a space to sit took a lot of time at each facility. In many facilities, finding working space for the teams was a problem, and staff reorganized their working offices to accommodate them with at least a table and chairs;
- Poor handwriting in some patient files consumed more time. Local staff assigned to help the data collection teams were helpful in deciphering the handwriting;
- The volume and intensity of work to retrieve data resulted in the need to work weekends. This meant that facilities kindly provided one member of staff to come to the facility and open the clinic to provide the teams with access to the files;
- Some patients and their records had been returned to the HIV and AIDS clinic. Mothers are transferred back to the HIV and AIDS clinic for treatment 24 months after: having successfully delivered an HIV-free baby; having a miscarriage; or having a baby who dies. We then had to retrieve the files from this clinic, and some of the clinics had very poorly organized files. A small number of files in most facilities could not be located;
- Some patient CTC numbers were wrongly written during baseline data collection, which was revealed when the name and number on the tablet were matched with

the actual file information. We corrected it in the field, but it led to some patients having a different baseline and endline study identification (ID) number. We linked these files during data analysis; and

- We sought to identify a newly treated patient cohort of up to five patients per facility per month during the endline data collection. However, many of the smaller clinics had fewer than five new patients a month. The data collectors took all available patients that met the entry criteria. Overall, we found a sufficient number of patients to conduct the planned analysis of the intervention's impact on missed visits early in the treatment process.

3.2.7 Data cleaning

We undertook the following steps to load the anonymized data extracted from the study server in Tanzania and to examine their consistency, quality and completeness:

- Load data from Excel transfer files to Stata files (patient and visit);
- Search for, list and resolve duplicate study IDs in the patient file;
- Search for and resolve duplicate or unmatched IDs in the endline file compared with the baseline file;
- Connect patient file with visit file and remove records that cannot be linked by baseline or endline study ID;
- Remove visits outside of the defined study period;
- Identify and resolve visits with duplicate dates;
- Search for and correct logical errors in entering months and years in study dates;
- Impute missing visit dates when possible, based on days of medication dispensed;
- Search for and resolve duplicates or near duplicates in terms of study dates;
- Examine distribution of days dispensed by facility to look for out-of-range values;
- Where possible, impute missing days dispensed, assuming that medicines are dispensed at every encounter according to standard practice;
- Overlay study design (begin, intervention and end dates) and examine monthly time series of visits;
- Search for and resolve errors in ART start dates, if possible; and
- Examine all study variables for missing data and for logical distributions.

3.3 Qualitative data collected

In addition to assessing quantitative changes in measures of clinic attendance, medication adherence and dropout, we also conducted semi-structured interviews with key district health officials and clinic staff on perceptions of clinic efficiency, problems in adherence and retention, and patient engagement with care at baseline and post-intervention. In intervention clinics, we interviewed staff about whether the intervention was acceptable and implemented efficaciously. We also carried out brief surveys with women receiving ART at Option B+ clinics to learn their perceptions of clinic processes as well as barriers to clinic attendance and adherence.

3.4 Methods used to analyze the data

We first summarized patient characteristics and baseline outcome rates in the cohorts of experienced and newly treated patients in intervention and control health facilities,

comparing the groups statistically using chi-square tests. We then used generalized estimating equation (GEE) models that adjusted for multiple visits per patient to examine key bivariate and multivariate predictors of missing a baseline visit. We next summarized the rates of missed visits and medication availability (measured as percentage of days covered by ARVs) in the pre-intervention and post-intervention periods among established patients by study group and by health facility.

We used three rigorous statistical approaches to evaluate the effects of the intervention: ITS with comparison series analysis; GEE DiD estimation; and Kaplan–Meier survival curves with accelerated Cox failure time models. Models were adjusted for possible pre-post changes in outcomes in the control group and all models controlled for clustering.

We used ITS with comparison series to display baseline to endline monthly rates of our study outcomes. We defined the beginning of the post-intervention period as 1 September 2015, a month after training ended, because the intervention could not affect patients until they presented for their next monthly visit. We considered the entire period after this as the post-intervention period. Because additional improvement took place with supervision visits, the overall intervention impacts may be underestimated, although the ITS models are able to estimate the increasing effect as a post-intervention slope changes. To determine relative effects in the intervention versus control facilities, we calculated the differences in monthly rates (intervention minus control) and used ITS segmented regression models to estimate post-intervention changes in level and trend of these differences compared with baseline.

In studies using an ITS design, the primary threat to validity is a factor that changes at the same time as the intervention, such as an external co-intervention or a sudden change in a population characteristic in one or both study groups. The randomized design reduces the possibility that an external co-intervention could be responsible for observed effects.

To examine whether patient dropout and associated changes in patient characteristics might explain effects, we conducted two secondary analyses. First, we estimated the intervention effects in the subgroup of continuous patients who had a visit in 2016 near the end of follow-up, comparing these with the estimated effects in the overall study population. If effects remain consistent in the continuous group, then differential dropout in the two groups is unlikely to be a confounder. Second, we examined the monthly prevalence of key population characteristics among patients with a visit in the intervention and control facilities to detect any discontinuities at or near the time of the intervention. No evidence of discontinuities makes it impossible for these population characteristics to be confounders of the estimates from the primary ITS analyses.

Wide variations in the monthly rates of missed visits might make it difficult to assess baseline trends and changes in trend reliably. We therefore also used patient-level GEE DiD models to estimate pre-post differences in the intervention versus control facilities. These models adjusted for patient covariates and also controlled for correlated observations due to multiple measurements from individual patients. DiD analysis is a more traditional method for analyzing data from cluster randomized trials, although it does not account for possible differences in trend between clusters at baseline or dynamic effects after the intervention (Fretheim et al. 2013; 2015). Combining the

primary ITS analyses with the GEE DiD models provides a robust way to assess intervention impacts both visually and statistically.

Among newly treated patients, we used Kaplan–Meier and accelerated failure time methods to assess the impact of appointment systems on missed visits of various durations, including gaps greater than 60 days (defined by the Tanzania HIV and AIDS program as loss to follow-up). We used Kaplan-Meier survival curves to depict the time elapsed until these outcomes. We used accelerated failure time models that allow average failure time to be estimated and compared. Our contrast of interest is the time-to-event in the post-intervention period in intervention versus control patients, compared with the time-to-event in the baseline period in intervention versus controls. Because this was a randomized trial, we can infer that any changes in the differences between groups in the post-intervention period are attributable to the intervention.

3.5 Qualitative assessment

During baseline data collection, the qualitative team conducted semi-structured interviews with clinic staff and district health officials in the intervention districts. These were about: (1) their perceptions regarding clinic efficiency, problems in adherence and retention, and engagement with care; and (2) how patients who miss appointments are recognized, what is done in response and what potential local resources may exist (e.g. community HIV support programs, community health workers) to follow up. At least 5 interviews of women on ART were planned at each facility, 2 district staff members in each district, and 2 clinic staff members at each facility.

During the follow-up assessment, the team again conducted semi-structured interviews with district health officials, clinic staff and patients, this time in both intervention and control groups, about their perceptions regarding clinic efficiency, problems in adherence and retention, and engagement with care. The teams also questioned staff in the intervention clinics about their perceptions of the intervention and its effects and in control clinics about whether clinic procedures have changed in the previous seven months and whether there was any awareness of the interventions implemented in the other districts.

During both assessments, data collectors conducted semi-structured exit interviews with the women on ART to explore perceived barriers to attendance and medication adherence and their perceptions about clinic efficiency and communication with the care team. This sample size is not sufficient to allow quantitative comparisons between intervention and control groups; however, we can explore possible changes in patient perceptions following an intervention intended to make clinic care more patient-centered.

Our qualitative approach was rooted in the principles of grounded theory (Strauss and Corbin 1994). We opted for semi-structured interviews over other data collection methods because it was more convenient for district and clinic staff to be interviewed at their workplace and for women to be interviewed as they exited the health facility. The interview method took an inductive approach that allowed participants to report issues related to clinic efficiency and barriers to adherence and retention, while we probed for necessary information (Silverman 2006). Research assistants used recording devices, but also took notes during interviews, which they later expanded. Although we did not

use verbatim transcripts, we systematically analyzed the data in sequence and used it to inform subsequent collection.

We determined our sample size using saturation sampling, which involves interviewing participants until no new information comes from the responses (Tuckett 2004).

4. Results

4.1 Quantitative assessment

4.1.1 Study samples

During the baseline survey, we identified 1,226 women in control facilities and 1,922 women in intervention facilities who were on ART for at least 6 months (established patients). Over time, women dropped out of the baseline sample for reasons including death, moving to another location, transferring to another treatment center and unknown loss to follow-up. For our secondary analysis of the effects of the intervention among patients who were continuous in treatment, we identified 970 (79.1%) and 1,433 (74.4%) women in control and intervention facilities, respectively, who were still on treatment in the same facility in 2016.

Table 4 compares the baseline characteristics of established patients and rates of study outcomes for these patients in the intervention and control groups, and also compares the characteristics of patients who continued in treatment versus those who did not in the intervention and control groups.

Compared with the control group, women in intervention facilities were somewhat younger (60.2% versus 52.4% of patients were aged 30 or under) and had initiated ART at an earlier WHO stage (57.5% versus 48.0% at WHO stage 1). In addition, the baseline rates of missing visits by seven or more days tended to be slightly higher in the intervention group, and the proportion of days covered by ART slightly lower. However, despite statistical differences between the groups due primarily to the large sample sizes, women in the intervention and control groups exhibit few meaningful differences.

Table 4 also compares baseline characteristics and outcomes between women who remained in treatment through the end of the study versus those who dropped out, in both the control and the intervention groups. Women who dropped out over the course of the study also tended to be somewhat younger, initiated ART at an earlier WHO stage, and had higher baseline rates of missed visits than their peers who remained in treatment. These differences between women who dropped out and those who remained in treatment were similar in the control and the intervention groups.

During the endline survey, we also identified a sample of women who had initiated ART during the course of the study. Overall, we included 109 women in control facilities and 120 women in intervention facilities who had initiated ART in the 6–12 months before 1 July 2015 (pre-intervention), and 180 and 204 women in control and intervention facilities, respectively, who had initiated in the 6 months after 1 August 2015 (post-intervention). Women who initiated in July 2015, who would have less than one month of follow-up prior to the beginning of the intervention, were excluded. We collected up to 180 days of follow-up visit data and dispensing data after treatment initiation for these samples of newly treated women.

Table 4: Baseline characteristics and unadjusted outcomes among established patients, and by subgroups continuing or not continuing treatment through January 2016

	All patients			Control group			Intervention group		
	Control	Intervention		No 2016 visit	2016 visit		No 2016 visit	2016 visit	
Baseline N of patients	1,226	1,924		256	970		492	1,432	
Age			p < 0.001			p = 0.021			p < 0.001
< 20 years	4.8%	8.2%		6.6%	4.3%		12.0%	6.8%	
21–30 years	47.6%	52.0%		51.2%	46.7%		55.5%	50.8%	
31–40 years	40.7%	35.8%		34.0%	42.5%		30.3%	37.7%	
> 40 years	3.5%	1.7%		2.7%	3.7%		1.2%	1.9%	
Missing	3.3%	2.3%		5.5%	2.8%		1.0%	2.8%	
Marital status			p = 0.021			p = 0.045			p = 0.050
Single	8.7%	9.1%		6.6%	9.3%		11.2%	8.4%	
Married/cohabiting	62.2%	57.0%		64.8%	61.4%		59.4%	56.2%	
Divorced/widowed	4.2%	4.3%		1.6%	5.0%		3.5%	4.5%	
Missing	24.9%	29.7%		27.0%	24.3%		26.0%	30.9%	
WHO stage at treatment initiation			p<0.001			p = 0.030			p < 0.001
1	48.0%	57.5%		54.7%	46.2%		67.3%	54.2%	
2	19.7%	12.9%		20.3%	19.6%		11.0%	13.6%	
3	20.0%	15.8%		15.6%	21.1%		10.2%	17.7%	
4	4.4%	2.0%		2.0%	5.1%		0.2%	2.6%	
Missing	7.9%	11.9%		7.4%	8.0%		11.4%	12.0%	
Year of ART initiation			p = 0.11			p = 0.367			p = 0.055
2012	4.7%	3.2%		1.6%	5.5%		2.4%	3.5%	
2013	24.8%	26.9%		26.6%	24.3%		31.3%	25.4%	
2014	67.7%	67.5%		68.4%	67.5%		63.6%	68.8%	
2015	2.9%	2.4%		3.5%	2.7%		2.6%	2.3%	
Year of delivery			p = 0.80			p = 0.056			p < 0.001
2013	9.3%	8.7%		7.4%	9.8%		6.9%	9.3%	
2014	42.7%	42.2%		29.3%	46.2%		29.5%	46.6%	
2015	24.7%	23.9%		14.1%	27.5%		12.4%	27.9%	

2016	9.0%	9.7%		9.8%	8.8%		12.0%	8.9%	
NA/missing	14.4%	15.5%		39.5%	7.7%		39.2%	7.3%	
Baseline N of visits	12,528	18,332		2,240	10,288		4,092	14,240	
% visits missed	39.2%	37.0%	p < 0.001	43.5%	38.2%	p < 0.001	41.1%	35.8%	p < 0.001
% missed by 3+ days	27.3%	27.1%	p = 0.714	33.0%	26.0%	p = 0.60	31.7%	25.7%	p < 0.001
% missed by 7+ days	17.3%	19.4%	p < 0.001	23.6%	15.8%	p < 0.001	24.7%	17.8%	p < 0.001
% missed by 15+ days	12.5%	15.6%	p < 0.001	18.6%	11.2%	p < 0.001	21.2%	14.0%	p < 0.001
% missed by 60+ days	3.3%	4.4%	p < 0.001	9.3%	1.9%	p < 0.001	11.1%	2.5%	p < 0.001
Baseline months of treatment	14,519	22,416		2,728	11,791		5,259	17,157	
Avg proportion of days covered	86.7%	83.3%	p < 0.001	86.4%	86.8%	p = 0.500	83.1%	83.5%	p < 0.447
% with PDC 80% or more	81.4%	76.8%	p < 0.001	81.5%	81.4%	p = 0.841	76.6%	76.9%	p = 0.594
% with PDC 95% or more	69.3%	63.8%	p < 0.001	69.7%	69.2%	p = 0.606	64.1%	63.8%	p = 0.649

Note: P-values report the results of chi-square tests comparing baseline patient characteristics and baseline outcomes between intervention and control groups (left), and between patients who drop out versus remain in the sample in each group (middle and right).

Table 5 summarizes the characteristics of patients who newly initiated ART in the intervention and control facilities. The newly treated women in both study groups are generally similar. For newly treated patients, the intervention facilities had a higher percentage of women who were divorced or widowed, while control facilities had a higher percentage of missing data about marital status. The impact of the intervention among newly treated patients is discussed following the findings among established patients.

Table 5: Baseline characteristics of patients initiating treatment on ART before 1 July 2015 (pre) and after 1 August 2015 (post)

	Start before 1 July 2015			Start after 1 Aug 2015		
	Control	**Intervention**		**Control**	**Intervention**	
N	108	120		181	204	
Age			p = 0.97			p = 0.33
< 20years	14.8%	14.2%		13.3%	9.8%	
21–30 years	55.6%	53.3%		62.4%	64.7%	
31–40 years	28.7%	31.7%		23.2%	25.5%	
> 40 years	0.9%	0.8%		1.1%	0.0%	
Missing	-	-		-	-	
Marital status			p < 0.001			p = 0.003
Cohabiting	13.0%	12.5%		14.9%	16.2%	
Divorced	1.9%	0.8%		1.7%	2.0%	
Married	65.7%	64.2%		63.5%	58.8%	
Single	7.4%	8.3%		9.9%	8.8%	
Widow	0.9%	14.2%		2.8%	12.3%	
Missing	11.1%	0.0%		7.2%	2.0%	
WHO stage at treatment initiation			p = 0.26			p = 0.48
1	80.6%	85.8%		81.8%	86.8%	
2	7.4%	8.3%		12.7%	10.3%	
3	12.0%	5.8%		5.0%	2.5%	
4	-	-		0.6%	0.5%	
Missing	-	-		-	-	
Year of ART initiation			p = 0.34			p = 0.18
2014	78.7%	73.3%		-	-	
2015	21.3%	26.7%		93.9%	90.2%	
2016	-	-		6.1%	9.8%	
Year of delivery			p = 0.01			p = 0.13
2014	27.8%	17.5%		2.2%	0.0%	
2015	60.2%	67.5%		33.7%	38.7%	
2016	12.0%	8.3%		62.4%	57.8%	
NA/missing	0.0%	6.7%		1.7%	3.4%	

Note: All p-values report the results of chi-square tests comparing patient characteristics between groups.

4.1.2 Predictors of baseline missed visits

Table 6 presents results from GEE models predicting the likelihood of missing a visit at baseline. Overall, patients in the intervention group had a lower odds of missing a baseline visit compared with controls (odds ratio (OR) = 0.91; 95% confidence interval [CI]: 0.86 to 0.97). Women who initiated ART at WHO stage 4 were also less likely to miss visits (OR = 0.84; CI: 0.72 to 0.99), as were women who initiated in 2015 versus those who initiated treatment before 2013. Most importantly, there were large variations in the likelihood of missed baseline visits across facilities. In multivariate models, only the facility-level variations in the odds of missed visits remained significant.

Table 6: Odds ratios (95% CI) from GEE models predicting missed baseline visits

	1	2	3	4	5	6	7	8
Number of visits in model	28,545	25,793	24,514	27,786	20,729	28,545	28,545	15,853
Intervention group	0.91** [0.86,0.97]							0.81 [0.65,1.01]
WHO stage 2 at initiation		1.20*** [1.09,1.31]						1.08 [0.96,1.22]
WHO stage 3		0.97 [0.89,1.06]						0.94 [0.83,1.05]
WHO stage 4		0.84* [0.72,0.99]						0.88 [0.73,1.06]
Post-delivery visit			0.99 [0.93,1.06]					1.04 [0.96,1.13]
Age 21–30 years				1.09 [0.96,1.24]				1.05 [0.89,1.24]
Age 31–40 years				1.04 [0.92,1.19]				1.02 [0.86,1.21]
Age 40 and above				1.1 [0.87,1.39]				1.17 [0.89,1.54]
Married/cohabiting					1.1 [0.99,1.23]			1.12 [0.98,1.26]
Divorced/widowed					1.08 [0.90,1.29]			0.99 [0.80,1.22]
Started ART in 2013						1.03 [0.86,1.23]		1.12 [0.88,1.43]
Started ART in 2014						1.01 [0.85,1.20]		1.11 [0.88,1.40]
Started ART in 2015						0.66** [0.50,0.88]		0.86 [0.58,1.26]
Kiwanja Mpaka Health centre							0.99 [0.83,1.17]	1.19 [0.94,1.50]

	1.12	1.15
Mbeya Regional Hospital	[0.93,1.35]	[0.90,1.47]
	1.34**	1.48*
Meta Hospital	[1.12,1.60]	[1.07,2.05]
	1.32**	1.44**
Ruanda Health Centre	[1.11,1.56]	[1.14,1.81]
	1.41***	1.70***
Chunya District Hospital	[1.18,1.69]	[1.32,2.20]
	1.19*	1.28*
Mwambani DDH	[1.01,1.40]	[1.02,1.62]
	0.82*	0.97
Ipinda Health Centre	[0.68,0.98]	[0.76,1.24]
	1.41***	1.50***
Kyela District Hospital	[1.20,1.65]	[1.18,1.90]
	0.43***	0.48*
Itaka Dispensary	[0.35,0.54]	[0.27,0.84]
	0.81*	0.89
Mlowo Dispensary	[0.67,0.97]	[0.70,1.14]
	0.88	1.01
Vwawa District Hospital	[0.75,1.04]	[0.81,1.26]
	0.79*	0.89
Chimala Mission Hospital	[0.63,0.99]	[0.62,1.28]
	1.65***	1.43**
Mbarali District Hospital	[1.39,1.96]	[1.15,1.79]
	0.88	0.77*
Small holders Dispensary	[0.71,1.08]	[0.60,1.00]
	1.03	0.97
St Bakita Health Centre	[0.82,1.30]	[0.73,1.29]
	0.80*	0.73*
Madibira Health centre	[0.66,0.97]	[0.57,0.94]
	1.46***	1.40**
Kamsamba Health Centre	[1.18,1.80]	[1.10,1.79]

	1.17	1.08
Tunduma Health Centre	[0.99,1.37]	[0.86,1.35]
	1.79***	1.74***
Igogwe Mission Hospital	[1.47,2.17]	[1.30,2.34]
	0.91	0.83
Tukuyu District Hospital	[0.76,1.09]	[0.66,1.03]
	0.8	0.86
Katete Dispensary	[0.61,1.06]	[0.55,1.35]
	1.34*	1.15
Mbalizi JWTZ Hospital	[1.05,1.69]	[0.81,1.63]
	1.12	1
Mbalizi Mission Hospital	[0.95,1.32]	[1.00,1.00]

Note: Reference categories: control group; WHO stage 1 at initiation; pre-delivery visit; age 20 and under; single; started ART before 2013; and Igawilo Health Centre.

*p < 0.05, **p < 0.01 and ***p < 0.001.

4.1.3 Summary of pre-post visits and outcomes

Table 7 summarizes the number of patients, visits and the average values of the eight study outcomes by study period for the intervention and control groups overall, and for individual health facilities. This data, which is not adjusted for baseline differences between groups or for the different numbers of visits contributed by individual patients, is presented for comparison purposes only. Overall, 1,604 of 1,924 women (83.4%) in the intervention group and 1,065 of 1,226 women (86.9%) in the control group whom we identified in the baseline survey had 1 or more visits in the post-intervention period (after 31 August 2015). The average number of visits during the entire study period was 14.9 for women in the intervention group and 15.6 for women in the control group.

Averaged across all health facilities, the rate of missed visits for women in the intervention group declined slightly from 36.5% to 34.4% after the start of the intervention. For women in the control group, the rate of missed visits increased from 38.9% to 45.5% during the same period. A similar pattern was observed for visits missed by three or more days (26.7% pre to 26.3% post in the intervention facilities; 27.0% to 35.0% in the control facilities). Women who miss a visit by seven days or more have a higher likelihood of having run out of medicines; overall, this rate increased in the intervention group (19.1% to 21.1%) but increased much more substantially in the control group (16.9% to 26.8%). We observed similar large differences in the pre-post changes in intervention versus control facilities for missing visits by 15 days or more (a period when women are at higher risk for viral rebound) and by 60 days or more (when patients are defined by WHO and by most ART programs as officially lost to follow-up).

The overall success in avoiding missed visits and maintaining women on ARV medications varied widely across health facilities in both groups. Rates of missed baseline visits varied from 21% to 44% among intervention facilities and from 30% to 48% among control facilities, with similar variation in the rates of missed visits of other durations. Baseline rates of patients being lost to follow-up varied from 2% to 7% in intervention and 2% to 6% in control facilities. In addition, response to the intervention appeared to vary widely across facilities in the intervention group. For example, four facilities (6, 8, 9 and 11) experienced reductions in missed visits of between 9 and 13 percentage points; two (7 and 12) experienced smaller reductions; while other mainly large, urban facilities remained the same or had small increases. In contrast, rates of missed visits declined slightly in only two control facilities (13 and 17), while six (15, 18, 21, 22, 23 and 24) increased by 10 to 13 percentage points. Adjusted analyses of variations in intervention response are reported below and possible reasons are discussed using qualitative data.

4.1.4 An assessment of the likelihood of differential attrition between the intervention and control groups

Dropout could influence average outcome rates over time and differential dropout could distort the apparent pre-post differences between groups. We examined study outcomes in women who continued treatment through at least January 2016 (Table 8). The findings in this continuous group of patients generally mirrored those in the overall sample. The overall rate of missed visits for continuous women in the intervention group declined from 35.2% to 33.6% following the intervention, while the overall rate of missed visits among controls increased from 38.0% to 45.0%. We observed similar larger increases in missed visit rates in control facilities for visits missed by 3, 7 or 15 or more days. The rates of

missing visits by 60 or more days during the final 3 months of follow-up were small and unlikely to be informative. The facility-specific baseline levels and patterns of pre-post change in missed visits in continuous patients were essentially identical with those in the overall group.

Table 7: Summary of patients, visits and outcome measures before and after the start of the intervention among all patients identified in the baseline assessment

		Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Intervention																					
1	Facility 1	202	145	1,921	817	35.6%	36.8%	26.3%	29.4%	20.6%	23.7%	18.8%	20.0%	6.3%	6.9%	81.9%	85.2%	74.2%	79.3%	62.1%	56.6%
2	Facility 2	189	168	1,978	1,054	35.4%	38.8%	23.5%	28.9%	14.0%	23.6%	10.0%	18.5%	2.3%	2.9%	87.8%	83.0%	83.6%	77.9%	62.9%	53.5%
3	Facility 3	115	88	1,013	551	37.8%	38.5%	29.1%	27.8%	23.5%	23.4%	20.7%	19.2%	7.3%	3.7%	79.1%	84.6%	71.9%	77.5%	57.8%	66.8%
4	Facility 4	140	116	1,213	584	42.7%	49.3%	37.4%	44.5%	30.6%	38.4%	23.4%	29.3%	6.4%	9.0%	77.0%	70.2%	69.6%	58.3%	52.7%	45.0%
5	Facility 5	199	166	1,914	1,087	42.5%	43.5%	28.2%	30.1%	16.5%	21.5%	12.1%	15.2%	3.4%	2.7%	87.9%	89.0%	82.8%	85.1%	70.8%	66.2%
6	Facility 6	132	115	1,182	791	43.4%	30.2%	33.8%	24.8%	27.0%	20.7%	21.7%	16.5%	5.6%	2.4%	78.8%	89.2%	69.3%	84.0%	56.1%	75.4%
7	Facility 7	196	179	1,736	1,178	40.0%	31.7%	29.8%	23.4%	22.1%	18.9%	17.9%	15.1%	3.6%	2.6%	79.2%	90.2%	69.4%	87.1%	56.6%	72.6%
8	Facility 8	118	90	1,194	633	31.7%	22.9%	22.9%	14.7%	15.7%	11.8%	11.5%	8.9%	3.8%	2.1%	88.0%	90.4%	82.9%	86.0%	74.8%	80.6%
9	Facility 9	199	167	1,794	929	44.4%	31.2%	32.6%	22.2%	24.6%	18.2%	20.8%	13.0%	6.3%	3.1%	77.3%	76.2%	69.2%	72.4%	49.0%	49.5%
10	Facility 10	101	96	1,027	580	19.9%	26.2%	15.8%	20.7%	13.1%	14.3%	11.9%	10.8%	3.1%	1.8%	85.1%	86.8%	82.7%	81.3%	70.0%	58.4%
11	Facility 11	127	113	1,346	654	32.3%	24.0%	20.8%	19.3%	11.2%	16.4%	8.5%	12.3%	1.9%	6.0%	91.9%	93.4%	87.7%	91.0%	80.7%	85.3%
12	Facility 12	206	161	2,013	1,036	32.6%	29.8%	24.1%	22.5%	16.7%	15.5%	12.7%	9.6%	4.0%	2.0%	88.0%	91.2%	83.8%	87.4%	75.9%	80.4%
	Intervention total	**1,924**	**1,604**	**18,331**	**9,894**	**37.0%**	**33.8%**	**27.1%**	**25.6%**	**19.4%**	**20.3%**	**15.6%**	**15.4%**	**4.4%**	**3.5%**	**83.4%**	**85.7%**	**77.1%**	**80.8%**	**63.6%**	**65.2%**
Control																					
13	Facility 13	79	69	766	450	30.5%	27.8%	19.8%	18.5%	13.1%	14.4%	11.6%	9.6%	3.8%	1.9%	86.5%	89.9%	80.8%	85.9%	69.2%	66.5%
14	Facility 14	198	174	1,983	992	47.6%	52.7%	31.4%	36.7%	19.6%	24.1%	14.9%	19.9%	3.7%	4.2%	83.7%	85.5%	77.1%	81.1%	64.4%	64.0%
15	Facility 15	36	34	416	188	32.9%	37.8%	20.9%	26.2%	11.8%	19.3%	7.0%	18.4%	1.4%	8.8%	93.2%	89.7%	89.9%	86.5%	78.6%	75.0%
16	Facility 16	59	57	570	363	38.2%	43.0%	32.5%	33.0%	23.2%	21.4%	17.0%	15.1%	4.6%	2.4%	77.7%	86.2%	69.3%	80.3%	57.9%	68.7%
17	Facility 17	82	76	936	526	30.0%	22.1%	17.3%	18.4%	8.9%	15.5%	5.8%	10.9%	1.4%	1.3%	94.4%	93.6%	91.4%	90.4%	85.2%	85.9%
18	Facility 18	58	52	562	258	47.0%	62.0%	35.1%	47.6%	23.7%	38.1%	19.2%	30.3%	5.2%	7.9%	81.6%	67.6%	74.6%	57.8%	56.7%	31.1%
19	Facility 19	204	162	2,036	914	38.9%	41.7%	30.5%	38.8%	21.6%	35.4%	16.3%	27.3%	4.2%	7.0%	85.1%	76.9%	79.2%	67.4%	67.5%	58.0%
20	Facility 20	88	72	852	441	49.5%	49.2%	39.2%	35.6%	22.9%	28.1%	14.9%	20.4%	4.0%	2.1%	84.1%	82.4%	78.0%	75.5%	58.1%	54.8%
21	Facility 21	118	106	1,272	689	34.2%	43.1%	19.7%	30.1%	10.3%	20.9%	7.2%	15.9%	1.9%	2.9%	91.1%	90.8%	88.8%	88.6%	72.6%	69.7%
22	Facility 22	64	53	737	322	30.9%	38.8%	22.1%	29.8%	12.6%	20.7%	6.4%	16.1%	1.6%	11.1%	93.8%	96.8%	90.4%	94.2%	85.7%	90.7%
23	Facility 23	64	59	588	294	42.9%	55.4%	29.9%	40.5%	21.8%	28.2%	17.0%	21.6%	4.6%	7.0%	79.6%	79.3%	73.4%	71.5%	55.7%	58.2%
24	Facility 24	176	151	1,808	838	38.7%	50.8%	25.8%	37.9%	15.9%	26.5%	11.1%	17.6%	2.7%	4.4%	89.9%	87.8%	85.4%	83.0%	77.0%	71.9%
	Control total	**1,226**	**1,065**	**12,526**	**6,275**	**39.2%**	**44.0%**	**27.3%**	**33.3%**	**17.2%**	**24.9%**	**12.5%**	**18.8%**	**3.2%**	**4.6%**	**86.6%**	**85.2%**	**81.4%**	**79.7%**	**69.1%**	**65.7%**
		3,150	**2,669**	**30,857**	**16,169**	**37.9%**	**37.8%**	**27.1%**	**28.6%**	**18.5%**	**22.1%**	**14.3%**	**16.7%**	**3.9%**	**4.0%**	**84.7%**	**85.5%**	**78.8%**	**80.3%**	**65.8%**	**65.4%**

Table 8: Summary of patients, visits and outcome measures before and after the start of the intervention among continuous patients who had at least one visit in the same facility after 1 January 2016

		N patients		N visits		% missed visits		% missed by 3 days		% missed by 7 days		% missed by 15 days		% missed by 60 days		Avg. PDC		% PDC ≥ 80		% PDC ≥ 95	
		Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Intervention																					
1	Facility 1	109	109	1,184	638	32.8%	35.3%	24.1%	28.1%	18.7%	22.3%	16.5%	17.7%	3.0%	2.4%	81.9%	84.5%	73.9%	78.4%	61.9%	57.2%
2	Facility 2	158	158	1,858	894	33.8%	40.6%	22.0%	30.5%	12.9%	24.9%	9.4%	18.9%	1.2%	2.3%	88.1%	83.1%	83.8%	78.6%	63.8%	53.1%
3	Facility 3	77	77	799	458	34.4%	38.9%	25.0%	28.6%	19.3%	23.9%	17.3%	19.1%	3.3%	1.5%	79.1%	84.1%	71.8%	77.4%	57.9%	65.8%
4	Facility 4	102	102	990	480	40.9%	49.6%	35.6%	44.7%	29.3%	38.0%	21.3%	28.4%	4.8%	6.3%	77.4%	71.0%	70.0%	59.4%	53.6%	44.6%
5	Facility 5	153	153	1,658	922	40.7%	43.9%	26.1%	31.1%	14.3%	22.3%	10.0%	15.3%	1.2%	1.8%	87.8%	89.1%	82.6%	85.2%	71.0%	66.3%
6	Facility 6	107	107	1,093	669	42.0%	29.6%	32.6%	24.4%	25.5%	20.7%	20.8%	16.3%	3.9%	1.4%	78.4%	88.5%	68.7%	83.1%	55.9%	73.2%
7	Facility 7	168	168	1,699	1,003	37.0%	33.0%	27.1%	24.5%	19.5%	19.6%	15.5%	15.5%	2.2%	1.6%	78.6%	89.8%	68.5%	86.5%	55.5%	72.3%
8	Facility 8	84	84	1,003	528	30.4%	21.3%	20.4%	13.8%	13.6%	11.3%	9.0%	8.6%	1.5%	1.2%	88.0%	90.0%	82.8%	85.8%	74.8%	79.9%
9	Facility 9	150	150	1,487	799	42.2%	30.4%	30.7%	21.2%	23.1%	17.0%	19.5%	11.1%	4.7%	1.2%	77.5%	76.1%	69.0%	72.3%	49.8%	48.1%
10	Facility 10	89	89	1,000	491	20.5%	24.0%	16.4%	17.9%	12.9%	12.2%	11.6%	9.1%	2.5%	0.2%	85.6%	85.6%	83.3%	80.2%	72.6%	55.4%
11	Facility 11	84	84	980	529	34.8%	19.9%	21.7%	16.0%	10.8%	13.1%	7.8%	8.3%	0.7%	1.2%	91.7%	93.7%	87.4%	91.2%	80.3%	85.4%
12	Facility 12	151	151	1,704	873	29.9%	30.1%	21.7%	22.0%	14.0%	16.0%	10.0%	9.6%	1.6%	1.1%	87.8%	91.0%	83.6%	87.1%	75.8%	79.9%
	Intervention Total	**1,432**	**1,432**	**15,455**	**8,284**	**35.2%**	**33.6%**	**25.2%**	**25.4%**	**17.5%**	**20.1%**	**13.7%**	**14.7%**	**2.4%**	**1.8%**	**83.4%**	**85.5%**	**76.9%**	**80.6%**	**63.9%**	**64.6%**
Control																					
13	Facility 13	65	65	719	394	27.4%	28.2%	16.4%	18.8%	10.8%	14.7%	9.5%	9.2%	2.1%	1.1%	86.6%	89.3%	80.9%	85.0%	69.4%	66.4%
14	Facility 14	163	163	1,833	836	46.4%	53.2%	29.8%	37.1%	17.5%	24.8%	12.9%	20.7%	2.5%	3.4%	83.8%	85.3%	77.1%	80.8%	64.8%	63.5%
15	Facility 15	23	23	292	131	30.1%	42.7%	18.8%	28.5%	9.6%	20.0%	4.5%	18.8%	1.0%	4.4%	93.1%	90.6%	89.6%	87.6%	78.1%	76.5%
16	Facility 16	55	55	579	321	39.0%	42.3%	32.1%	33.4%	22.6%	22.2%	16.6%	15.3%	4.3%	1.8%	77.8%	85.2%	69.4%	79.2%	57.9%	67.8%
17	Facility 17	72	72	906	449	28.6%	23.6%	16.3%	20.2%	7.7%	17.3%	5.1%	12.2%	0.8%	0.5%	94.3%	93.9%	91.2%	91.1%	84.6%	87.2%
18	Facility 18	46	46	493	217	46.7%	60.4%	34.5%	45.0%	23.5%	35.1%	18.7%	27.0%	4.5%	4.8%	83.2%	66.6%	77.1%	55.6%	59.4%	29.7%
19	Facility 19	144	144	1,624	759	36.1%	43.3%	27.6%	40.7%	18.8%	37.6%	14.3%	28.4%	2.1%	5.9%	85.3%	77.6%	79.3%	68.6%	67.5%	59.2%
20	Facility 20	70	70	775	381	47.1%	51.7%	37.8%	37.5%	20.6%	30.2%	13.0%	22.3%	1.9%	1.8%	84.3%	82.2%	78.0%	75.8%	58.6%	54.3%
21	Facility 21	99	99	1,171	579	33.3%	44.5%	18.4%	31.6%	9.4%	22.2%	6.4%	16.9%	0.9%	2.2%	91.0%	91.2%	88.6%	89.2%	72.6%	70.3%
22	Facility 22	43	43	560	245	32.5%	40.8%	22.0%	31.8%	11.8%	21.9%	4.8%	16.7%	0.2%	10.5%	93.7%	96.4%	90.3%	94.0%	85.8%	89.8%
23	Facility 23	52	52	525	238	43.4%	55.7%	29.9%	40.9%	20.4%	29.5%	16.0%	22.2%	3.2%	5.2%	79.5%	79.5%	73.1%	72.4%	54.8%	59.5%
24	Facility 24	138	138	1,616	697	38.0%	51.6%	24.6%	39.0%	14.4%	27.7%	9.3%	17.7%	1.2%	2.8%	89.8%	88.3%	85.1%	83.7%	77.3%	71.9%
	Control Total	**970**	**970**	**11,093**	**5,247**	**38.0%**	**45.0%**	**25.8%**	**34.3%**	**15.5%**	**26.0%**	**11.0%**	**19.3%**	**1.9%**	**3.4%**	**86.7%**	**85.2%**	**81.4%**	**79.9%**	**69.3%**	**65.9%**
		2,402	**2,402**	**26,548**	**13,531**	**36.4%**	**38.0%**	**25.5%**	**28.8%**	**16.7%**	**22.3%**	**12.6%**	**16.4%**	**2.2%**	**2.4%**	**84.7%**	**85.4%**	**78.7%**	**80.3%**	**66.0%**	**65.1%**

4.1.5 Changes in outcomes over time among established patients

Figure A1, available as an online appendix D, displays time series comparing the monthly rates of the missed visit and percentage of days covered (PDC) study outcomes among women receiving ongoing care in the intervention and control facilities before and after the start of the intervention, as well as the monthly differences in these rates.

During the baseline period, intervention and control groups were similar in both the level and trend of visits missed by more than 1, 3, 7 or 15 days, as illustrated by monthly differences in rates that hover near zero percent. However, the monthly rates of these outcomes in intervention and control facilities diverged after the start of the intervention, reaching differences in rates between groups of more than 10 percent by six months after the intervention. The relative differences between groups following the intervention are much less visible for the rates of patients lost to follow-up, as measured by missing visits by more than 60 days.

Of note, the sampling procedure for selecting established patients required a visit to the health facility in or around April 2016, so that the subsequent intervention effects could be studied in patients currently receiving care. The apparent worsening of missed visit rates among women in control facilities is a commonly observed phenomenon when sampling for service utilization shortly before an intervention. Because we sampled equivalently in both the intervention and control facilities, we would expect this effect of regression to the mean to apply equally in both study groups.

For the three study measures of days covered by dispensed medications, the apparent effects of the intervention are less visible. The average PDC remains at slightly more than 80% for the entire study period following the initial decline from 100% that is intrinsic to the start of adherence measurement. Intervention facilities had slightly lower average PDC than control facilities in the baseline period, but they averaged slightly higher than controls following the intervention. Similarly, the percentages of patients with PDC greater than or equal to 80% and PDC greater than or equal to 95% in intervention facilities remained below those of control facilities during baseline, but increased to surpass controls during the post-intervention period.

Figure A2, available as an online appendix D, displays the corresponding time series of study measures among continuous patients who were still in treatment at these health facilities in early 2016. The monthly rates of all outcomes, the relationships between rates in the intervention and control facilities, and the apparent effects of the intervention are essentially identical to the analyses that include all baseline patients.

Table 9 presents results of ITS analyses of the monthly differences between intervention and control groups for the cohort of established patients, as well as for the subgroup of patients who continued to visit the same facility in 2016. This table summarizes the primary results of the study, expressed as the relative changes in the eight study outcomes in the intervention group compared with the changes in the control group at six months following the intervention; all models control for baseline trends in both groups.

All models of missed visits of different duration identify significant declines in trend in intervention facilities following the intervention. The net estimated decreases in intervention versus control facilities at 6 months after the intervention are: 13.7

percentage points (95% CI: -15.4 to -12.1) for missing visits by 1 or more days; 12.5 percentage points (-14.7 to -10.4) for visit gaps of 3 days; 9.8 percentage points (-11.7 to -7.8) for 7 days; 8.7 percentage points (-11.1 to -6.4) for 15 days; and 3.3 percentage points (-4.8 to -1.8) for 60 days. Corresponding to the improved rates of appointment keeping and the more regular supply of medications, the PDC ITS models identify small non-significant gains in the trend of average monthly PDC (0.1 percentage points; CI: -1.1 to 1.4) and in the percentage of patients with rates of PDC greater than or equal to 80% (0.7 percentage points; CI: -1.2 to 2.6), and a significant increase in the percentage of patients with PDC greater than or equal to 95 percent (6.6 percentage points; CI: 4.7 to 8.4).

Once again, the findings of the ITS models of missed visits among women who continued in care into 2016 are essentially the same as those observed in the entire population, while the PDC models estimate slightly greater gains in medication adherence.

Table 9: Results of aggregate interrupted time series models predicting post-intervention changes in level and trend in the monthly differences between intervention and control groups, and the estimated difference in change of outcomes at six months after the start of the intervention

	Missed visits	Missed by 3+ days	Missed by 7+ days	Missed by 15+ days	Missed by 60+ days	Average PDC	% PDC ≥ 80	%PDC ≥ 95
All baseline patients								
Constant	-0.028***	0	0.038***	0.053***	0.016**	-0.072***	-0.095***	-0.067***
	[-0.03,-0.02]	[-0.01,0.01]	[0.03,0.05]	[0.04,0.07]	[0.01,0.03]	[-0.08,-0.06]	[-0.11,-0.08]	[-0.08,-0.06]
Baseline trend	0.001*	0	-0.002**	-0.003**	-0.001	0.005***	0.006***	0.001*
	[0.00,0.00]	[-0.00,0.00]	[-0.00,-0.00]	[-0.00,-0.00]	[-0.00,0.00]	[0.00,0.01]	[0.00,0.01]	[0.00,0.00]
Level change post	-0.028**	0	0.030**	0.047***	0.01	-0.029***	-0.030**	-0.055***
	[-0.05,-0.01]	[-0.02,0.02]	[0.01,0.05]	[0.02,0.07]	[-0.00,0.02]	[-0.04,-0.02]	[-0.05,-0.01]	[-0.07,-0.04]
Trend change post	-0.018***	-0.021***	-0.021***	-0.022***	-0.007***	0.005***	0.006***	0.020***
	[-0.02,-0.01]	[-0.02,-0.02]	[-0.03,-0.02]	[-0.03,-0.02]	[-0.01,-0.01]	[0.00,0.01]	[0.00,0.01]	[0.02,0.02]
Estimated change at 6 months after intervention	**-13.7% [-0.15,-0.12]**	**-12.5% [-0.15,-0.10]**	**-9.8% [-0.12,-0.08]**	**-8.7% [-0.11,-0.06]**	**-3.3% [-0.05,-0.02]**	**0.1% [-0.01,0.01]**	**0.7% [-0.01,0.03]**	**6.6% [0.05,0.08]**
Continuous patients								
Constant	-0.020***	0.008	0.046***	0.059***	0.018***	-0.071***	-0.094***	-0.075***
	[-0.03,-0.01]	[-0.00,0.02]	[0.04,0.05]	[0.05,0.07]	[0.01,0.02]	[-0.08,-0.06]	[-0.11,-0.08]	[-0.08,-0.07]
Baseline trend	0	-0.001	-0.003***	-0.004***	-0.002***	0.005***	0.006***	0.003***
	[-0.00,0.00]	[-0.00,0.00]	[-0.00,-0.00]	[-0.01,-0.00]	[-0.00,-0.00]	[0.00,0.01]	[0.00,0.01]	[0.00,0.00]
Level change post	-0.047***	-0.021*	0.011	0.029**	0.006*	-0.023***	-0.024**	-0.037***
	[-0.06,-0.03]	[-0.04,-0.00]	[-0.00,0.03]	[0.01,0.05]	[0.00,0.01]	[-0.03,-0.01]	[-0.04,-0.01]	[-0.05,-0.02]
Trend change post	-0.014***	-0.018***	-0.018***	-0.020***	-0.004***	0.005***	0.006***	0.018***
	[-0.02,-0.01]	[-0.02,-0.01]	[-0.02,-0.01]	[-0.02,-0.01]	[-0.01,-0.00]	[0.00,0.01]	[0.00,0.01]	[0.01,0.02]
Estimated change at 6 months after intervention	**-13.3% [-0.15,-0.12]**	**-12.8% [-0.16,-0.10]**	**-10.0% [-0.12,-0.08]**	**9.1% [-0.12,-0.07]**	**-1.7% [-0.03,-0.01]**	**0.9% [0.00,0.02]**	**1.4% [-0.01,0.04]**	**7.3% [0.05,0.10]**

95% CI in brackets

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

4.1.6 Potential confounders of ITS effects

To address the possibility that changes in patient characteristics near the time of the intervention may have explained some of the observed effects, we examined the proportion of patients with key observed population characteristics over time in the intervention and control groups (Figure A3, available as an online appendix D). There is no evidence of any discontinuities at the time of the intervention in either study group, and, more importantly, no evidence of any change in the relative differences in these characteristics between groups. Unmeasured population characteristics could have changed during this period, but that is unlikely in light of the stability of the trends in measured characteristics.

4.1.7 Generalized estimating equations models predicting changes in adjusted odds of study outcomes

To supplement the ITS modeling approach, we also conducted GEE DiD analyses examining the relative changes in the likelihood of missed visits or increases in adherence. These models are at the individual level, which allows adjustment for patient-level covariates that might explain some of the differences between groups; they also included terms to adjust for individual health facilities.

Table 10: Results of GEE difference in difference models predicting adjusted odds (95% CI) of study outcomes, all baseline patients and patients remaining in treatment in 2016

	Missed visits	Missed visits 3+ days	Missed visits 7+ days	Missed visits 15+ days	Missed visits 60+ days	Average PDC &	Percentage ≥ 80% PDC	Percentage ≥ 95% PDC
Among all patients included at baseline								
Number of visits/months in model	35,037	34,922	34,906	34,546	33,815	42,161	42,161	42,161
Post-intervention	1.28***	1.46***	1.82***	1.85***	2.17***	-0.02**	0.9	0.85**
	[1.19,1.37]	[1.35,1.58]	[1.67,1.98]	[1.68,2.04]	[1.78,2.65]	[-0.03,-0.00]	[0.80,1.01]	[0.77,0.94]
Intervention group	0.81*	0.98	1.30**	1.80***	2.41***	-0.08***	0.50***	0.47***
	[0.69,0.96]	[0.84,1.16]	[1.09,1.54]	[1.49,2.16]	[1.70,3.44]	[-0.10,-0.05]	[0.40,0.63]	[0.38,0.58]
Intervention X post	**0.69*** **	**0.66*** **	**0.63*** **	**0.57*** **	**0.51*** **	**0.05*** **	**1.54*** **	**1.30*** **
	[0.63,0.76]	**[0.60,0.73]**	**[0.56,0.70]**	**[0.50,0.65]**	**[0.40,0.65]**	**[0.03,0.06]**	**[1.33,1.78]**	**[1.15,1.47]**
Among patients still in treatment in 2016								
Number of visits/months in model	31,030	30,915	30,899	30,539	29,808	37,065	37,065	37,065
Post-intervention	1.27***	1.46***	1.84***	1.87***	1.99***	-0.02**	0.88*	0.83***
	[1.18,1.38]	[1.35,1.58]	[1.68,2.01]	[1.68,2.08]	[1.56,2.55]	[-0.03,-0.01]	[0.78,0.99]	[0.75,0.93]
Intervention group	0.76**	0.97	1.31**	1.87***	2.29**	-0.08***	0.48***	0.45***
	[0.63,0.92]	[0.80,1.17]	[1.08,1.60]	[1.51,2.31]	[1.37,3.81]	[-0.11,-0.05]	[0.37,0.62]	[0.36,0.57]
Intervention X post	**0.67*** **	**0.64*** **	**0.60*** **	**0.54*** **	**0.34*** **	**0.05*** **	**1.55*** **	**1.33*** **
	[0.60,0.74]	**[0.57,0.71]**	**[0.54,0.68]**	**[0.47,0.61]**	**[0.24,0.47]**	**[0.03,0.06]**	**[1.33,1.81]**	**[1.17,1.52]**

Note: All models adjusted for WHO stage at initiation, if visit is post-delivery, age category, year of ART initiation, and individual facility identifiers.

Average PDC is modeled as an average rate with a Gaussian distribution, and results are presented as rates rather than odds ratios.

Table 10 presents the results of the GEE models for both the overall study population and the subgroup of continuous patients. As was apparent in the data from monthly time series of these measures, the adjusted odds of missed visits were significantly higher in the overall study population in the post-intervention period, while the overall average PDC and the likelihood of covering greater than or equal to 80% or greater than or equal to 95% of days with medications were slightly but significantly lower after the intervention. However, relative to control patients, women who received care in intervention facilities had significantly lower post-intervention adjusted odds of missing a visit (0.69; 95% CI: 0.63 to 0.76), as well as of missing visits of various longer durations. Their estimated adjusted odds of missing a visit by 60 days and being considered lost to follow-up were half those of women in control facilities (0.50; CI: 0.39 to 0.65). Women in the intervention group were estimated to have slightly but significantly higher post-intervention adjusted odds of achieving greater than 95 percent adherence (1.31; CI: 1.16 to 1.48), which is the target level in ART. As in the ITS models, the findings in the women who continued in treatment in 2016 were essentially identical to those in the overall study population of established patients.

4.1.8 Changes in time until missed visits among newly treated patients

While the intervention focused primarily on improving appointment keeping and adherence among women on long-term ART therapy, we also examined its effects among women who were newly initiating treatment. While we expected attendance and adherence to be relatively higher during the early stage of treatment, especially for women who are pregnant at initiation, the intervention might still be effective in extending the time until a woman missed an appointment.

Figure A4, available as an online appendix D, presents survival plots comparing the unadjusted time until missed appointments of greater than 1, 3, 7 and 15 days during the first 180 days of treatment among women in the intervention and control facilities. Follow-up time in the post-intervention period was too short to reliably estimate time until missing a visit by 60 days or more. One column compares time until missed visits among intervention and control patients who initiated treatment in the pre-intervention period, while another column compares women who began treatment in the post-intervention period. The pre-intervention populations are censored at the time of the intervention to prevent contamination.

The pre-intervention populations appear to be identical in time until all missed visit outcomes. By 180 days of treatment, about 75% of both study groups had missed a visit, and about 50% had missed a visit by 15 days or more. In the post-intervention period, both the intervention and control groups demonstrated somewhat reduced likelihood of missing a visit, and especially of longer-term gaps in treatment. For example, only 25 percent of each group had missed an appointment by 15 days or more in the post-intervention period. The time until missing a visit, and especially of missing a visit by three days or more, appears to be extended in the intervention group following the intervention.

Table 11 presents results of adjusted Cox proportional hazards models comparing the time until missed visits of various durations in the pre- and post-intervention periods, with the intervention effect estimated by the intervention group variable. These adjusted models confirm the apparent effect observed in the survival plots. In the post-intervention

period, women in the intervention facilities have a lower hazard of missing a visit (-0.17; CI: -0.28 to -0.06) or missing by three or more days (-0.24; CI: -0.37 to -0.10) compared with counterparts initiating treatment in control facilities. The estimated intervention effects are not significant for longer duration gaps in treatment.

Table 11: Results of Cox proportional hazards models on time until missed visits of varying duration in cohorts of new patients initiating ART before and after the intervention in intervention versus control facilities

	Missed visit		Missed by 3+ days		Missed by 7+ days		Missed by 15+ days	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Intervention	0.06	-0.17**	0.01	-0.24***	0.12	-0.04	0.18*	-0.07
	[-0.05,0.18]	[-0.28,-0.06]	[-0.12,0.14]	[-0.37,-0.10]	[-0.02,0.25]	[-0.20,0.13]	[0.04,0.32]	[-0.27,0.13]
Age 21–30	0.44***	-0.17	0.16	-0.35***	0.14	-0.51***	0.03	0.05
	[0.25,0.62]	[-0.35,0.00]	[-0.03,0.35]	[-0.54,-0.15]	[-0.07,0.34]	[-0.74,-0.27]	[-0.18,0.24]	[-0.28,0.38]
Age 31–40	0.62***	-0.15	0.33**	-0.40***	0.11	-0.35*	-0.07	0.45*
	[0.42,0.81]	[-0.35,0.05]	[0.13,0.54]	[-0.63,-0.17]	[-0.12,0.33]	[-0.62,-0.08]	[-0.30,0.16]	[0.09,0.81]
Age 41+	0.01	0.58	0.14	0.86**	0.44	0.06	0.59	0.88*
	[-0.81,0.84]	[-0.02,1.17]	[-0.68,0.96]	[0.26,1.46]	[-0.38,1.27]	[-0.78,0.90]	[-0.24,1.42]	[0.01,1.75]
WHO stage 2	-0.07	0.29***	0.04	0.01	0.03	0.12	-0.12	-0.56**
	[-0.29,0.15]	[0.12,0.45]	[-0.18,0.27]	[-0.20,0.22]	[-0.22,0.28]	[-0.14,0.38]	[-0.39,0.15]	[-0.94,-0.18]
WHO stage 3	0.17	0.42**	0.24*	-0.70**	0.42***	-0.47	0.64***	-0.68
	[-0.04,0.39]	[0.14,0.70]	[0.01,0.47]	[-1.17,-0.24]	[0.18,0.66]	[-1.03,0.08]	[0.40,0.89]	[-1.38,0.03]
WHO stage 4		0.82*		1.24**		1.95***		2.18***
		[0.08,1.57]		[0.49,1.99]		[1.20,2.71]		[1.42,2.94]
Post-delivery	0.19**	0.11	0.23***	0.09	0.30***	0.07	0.35***	0.12
	[0.07,0.30]	[-0.01,0.22]	[0.10,0.35]	[-0.05,0.22]	[0.16,0.43]	[-0.10,0.24]	[0.20,0.49]	[-0.08,0.32]

Referent categories: Control group, age 20 and under, WHO stage 1 at initiation.

95% CI in brackets.

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

4.1.9 Heterogeneity of treatment effects

This cluster randomized trial was designed to examine effects at the group level rather than the facility level. The sample sizes of women in treatment at some facilities are relatively modest, so intervention impacts cannot reliably be estimated at that level. Nevertheless, as Tables 6 and 7 demonstrate, rates of missed visits and PDC varied substantially across facilities at baseline, and the effects of the intervention in the intervention group appeared to vary as well. We therefore ran individual adjusted GEE models examining the pre-post odds of study outcomes in each facility in the intervention and control groups. While these models are not controlled, they allow us to examine the changes from before to after the intervention, adjusted for patient-level covariates.

Figure A5, available as an online appendix D, presents the odds ratios and 95 percent CI from the post-intervention term of the 24 GEE models estimating the likelihood of a missed visit in each facility. In five of the intervention facilities and in one control facility, the odds of a missed visit are significantly lower after the intervention. Two intervention facilities and five control facilities demonstrated significantly higher odds of a missed visit in the post-intervention period. Findings from the supervisory reports and post-intervention interviews may provide useful information about the variations in effects by facility.

Using the fully specified GEE model estimating the impact of the intervention on the likelihood of a missed visit, we also tested for differential effects of the intervention by running the model within population subgroups stratified on the basis of our predictor variables: age category (≤ 30 versus 31 and above), WHO stage at initiation (1 or 2 versus 3 or 4), year initiating ART (2015 versus earlier), and whether a visit occurred before or after delivery. The stratification term was removed as a predictor in each model. None of the subgroups exhibited any evidence of differential effects and the confidence intervals of the terms estimating the effect of the intervention in these subgroups all overlapped.

Qualitative information from the four facilities that improved their attendance rates the most (facilities 6, 8, 9 and 11) provides differing strategies for success. We noted that facility 6 and 9 staff are working very closely with community organizations that follow missing patients very promptly, and that facility 6 had spread the workload more evenly, giving patients a choice of morning or afternoon appointments, which was appreciated by the patients we interviewed. In facility 8, staff had put much greater emphasis on tracing missing patients promptly, and after the intervention, insisted that patients come on their scheduled dates or go to the back of the queue when they showed up. In facility 11, they had noted that a lot of wives had not told their husbands their status, which led to more non-attendance. The staff started a program of couple counseling, with advice on how to live with HIV, which they claimed increased attendance.

Most of the facilities that did not show improvement in the intervention group are in Mbeya urban area. Interviews showed that urban populations are more transient than those in rural areas. The facilities also tended to be larger with both a zonal and a regional hospital. At such facilities, there is a rapid staff turnover, so that knowledge of how to operate the system may not last. In addition, with a large number of patients a computer-based system may be more functional than a paper-based system such as the one introduced.

We also noted that two of the control facilities had improved their performance (facilities 13 and 17). In facility 17, the staff were very motivated and had started using the registers and following missing patients through community organizations themselves. Facility 13 staff said that they had put a strategy in place last year to work closely with community organizations to ensure missing patients are followed up and brought back to care.

It seems that motivated staff, close liaisons with community organizations, rapid identification and tracking of missing patients, and improving the patient reception are all components of the success stories.

4.2 Qualitative data

Interviews at baseline only took place in the 4 intervention districts and 12 intervention facilities to avoid biasing the results. The endline study took place at both intervention and control districts and facilities. Our baseline study included 74 participants comprising 12 clinic staff members, 58 women on ART and 4 district staff members (Table 12). The endline study comprised 146 participants: 23 clinic staff, 115 women on ART (60 in intervention and 55 in control facilities) and 8 district staff members (Table 13).

Table 12: Sampling for baseline interviews

Districts	Women on ART	District staff	Clinic staff	Total
Mbeya Urban	24	1	5	32
Chunya	11	1	2	15
Kyela	11	1	2	15
Mbozi	13	1	3	18
Total	58	4	12	74

Table 13: Sampling for endline interviews

Intervention districts	Women on ART	District staff	Clinic staff	Total
Mbeya Urban	25	1	5	31
Chunya	10	1	2	13
Kyela	10	1	2	13
Mbozi	15	1	3	19
Total intervention	60	4	12	76
Control districts				
Mbeya Rural	9	1	2	12
Rungwe	9	1	2	12
Momba	14	1	3	18
Mbarali	23	1	4	28
Total control	55	4	11	70
Total	115	8	23	146

We grouped together findings from the clinic and district staff to explore perceived barriers to adherence and retention, clinic performance and district support to respective health facilities and perceived impact of the intervention. In the analysis, nine themes were identified around issues of adherence, health system challenges, appointments, missing patient follow-up and the effects of the intervention.

We then analyzed the interviews from women patients on their experience with ART and adherence and retention to care and perceived quality of services before and after the intervention.

Importantly, this intervention was not found to affect any other workings of the RCH facility in a negative way.

In summary, clinic staff appreciated the integration of HIV care and treatment in RCH Option B+ clinics as a way of assisting women living with HIV to access care at the same place, and were keen for improvement.

Before the intervention and in control clinics, staff reported several health system challenges that potentially contributed to poor adherence and retention. Topics frequently mentioned included too few staff trained on HIV, a lack of diagnostic equipment and a lack of privacy. The most commonly reported health system problem mentioned by both staff and patients was patients having to wait too long for care and service at health facilities. Both staff and women noted improvements during the intervention endline assessment as a result of the intervention. The most frequently noted improvements were: timeliness of care, treatment confidentiality, patient–provider interaction and reduced workload. An interesting finding was that despite women in intervention facilities reporting that they were unaware of the new appointment and tracking system, they did identify specific differences in the way they had been attended over the previous eight months.

With respect to adherence, before the intervention and in control clinics, all clinic staff noted problems with assessing treatment adherence. They rarely mentioned self-reports or pill count. After the intervention, ART adherence was given a higher priority by clinic staff particularly with the assistance from community outreach programs. Most clinics had some contact with community outreach programs of one sort or another. However, during endline data collection, we noted more commitment by such organizations in following and bringing missing patients back to care on time. We also noted staffs' commitment to monthly adherence assessments in endline intervention facilities.

A major issue for patient engagement was whether patients were consulted over a convenient date and time for their next appointment. At baseline, 6 health facilities reported discussing this with patients, but at endline, all 12 health facilities reported that they did so, and 5 clinics went further into negotiating with patients on the times of the day to come for the appointment.

We found in the baseline intervention clinics and some control clinics that the appointment registers were actually being used to arrange patients' appointments and identify missing patients, but it was clear that, although clinic staff were using both patient files and the registers, they were inappropriately filling them in. During the endline

assessment, we observed registers updated and filled in as recommended and correctly used to arrange appointments and identify and follow-up missing patients.

Appendix C includes a full report of the qualitative exercise.

4.3 Cost analysis

Many programs aim for an adherence level of 95 percent (Paterson et al. 2000). For days covered by dispensed medicine, after the intervention, there was an increase of 7.3 percentage points in more patients attaining 95 percent or better coverage relative to controls (Table 9). So, for the 1,443 women on treatment recorded by the assessments, we can say that an extra 105 women would be expected to achieve 95 percent of days covered.

The cost of this improvement depends considerably on who is doing the intervention and supervision visits. In our case, the people were traveling from Dar es Salaam to Mbeya, staying in hotels and hiring vehicles, which added considerably to the expense.

If we look at person-days (Table 14), we can see that for a training-level cadre, the training of the trainers took 2 days for each of the 4 trainers and 1 trainer of trainers (10 days); the 2-day trainings took 16 person-days, and each round of supervision took 5 days for 2 pairs (20 days). So that the whole intervention took 104 person-days in Mbeya, plus a total of 40 person-days traveling back and forth from Dar es Salaam. Without traveling, this works out to be 1 extra woman achieving 95 percent of days covered by dispensed medicine per 1 training-level cadre person-day.

Table 14: Person-days taken up for the intervention

	Training of trainers	Trainings	Super-vision 1	Super-vision 2	Super-vision 3	Super-vision 4	Travel days (Dar es Salaam to Mbeya)	**Total Less travel days**
Car hire	0	0	10	10	10	10	16	**40**
TOT trainer (1)	2	0	0	0	0	0	0	**2**
Trainers and supervisors (4)	8	16	20	20	20	20	40	**104**
Facility staff	0	48	12	12	12	12	0	**96**

Looking at facility-level staff for each facility, 2 staff members were trained over 2 days and spent half a day with supervisors in each of 4 rounds of supervision. So, for the 12 facilities, the intervention took up 96 days of facility staff time, which does not count the time they took to fill in the registers and follow up missing patients. Not including traveling from Dar es Salaam, roughly speaking, this works out at about 1 extra woman achieving 95 percent of days covered by dispensed medicine per 1 training-level cadre person-day and 1 facility staff p[[erson-day.

The overall cost of all of the trainings and supervision, including car hire, flights, hotels and other expenses, was approximately US$30,000. On this basis, we can also say that for our trial it cost around US$278 for 1 extra woman to achieve 95 percent of days covered by dispensed medicine. Second-line treatment is US$779 more expensive than first line for one year, so any degree of prevention of resistance is saving considerable sums (PEPFAR 2013).

The number of treatment failures this intervention would prevent is unclear, but it would be considerable. Adherence is inversely proportional to virological failure (Shet et al. 2016). For example, in a study in South Africa when 50% or less of prescriptions were filled, only 13% of 325 patients achieved viral suppression, whereas 73% of 997 patients achieved viral suppression if 100% of prescriptions were filled (Nachega et al. 2007). In addition, in an earlier work, virological failure was documented in 22% and 61% of patients with adherence of 95% or greater and 80%, respectively (Paterson et al. 2000).

However, if this intervention were scaled up, district and regional staff from the MOHSW and partner organizations would take on most of the work, and as discussed in a dissemination meeting in Mbeya, the initial training would be incorporated into routine supervision visits at each facility rather than conducted at an expensive central regional training, and the supportive supervision would be carried out the same way, so that the expense would in fact be minimal because the work would be absorbed into routine practices.

5. Discussion

The manual system of appointment tracking and subsequent community outreach for patients who miss appointments was low cost and relatively simple to implement with two days of training and subsequent supervisory visits. The intervention significantly improved appointment-keeping and consistent availability of antiretroviral medicines in the intervention group compared with the control group for patients on long-term ART. The facility staff were able to control their workload, rapidly identify missing patients, work with existing community organizations and bring missing patients back into care. At the same time, patients noted that they were able to choose convenient days for their appointments and wasted less time waiting in the clinic. These were very positive outcomes. There was a significant increase in the percentage of women with greater than 95 per cent coverage of dispensed medicines – more than 29 days of every 30. Although we were unable to determine whether they took their medicine correctly, we do know that, if patients do not have medicines in their possession, they cannot take them as required to treat their illness.

At baseline, 37% to 39% of appointments were not attended on time, varying from 21% at one facility to 48% at another, so there was considerable room for improvement. Averaged across all health facilities, the rates of missed visits of various durations for women in the intervention group declined following the intervention; whereas, for women in the control group, the rate of missed visits increased considerably during the same periods. The increase in the control group is not unexpected, and was due in part to the way that we selected women for the study. Because one of the inclusion criteria for the study for patients in long-term treatment at baseline was that they had recently attended the clinic, their initial attendance rates are by definition higher than average at that point in time, and regression to the mean took place over the ensuing months. The fact that the intervention group did not regress, and in fact, decreased their rate of missed visits further is strong evidence for the effectiveness of the intervention overall.

All of the analyses comparing results in the entire sample of baseline patients with those in the subgroup who continued to attend in or after January 2016 – thus eliminating the changing denominator due to women who had left treatment for a variety of unknown

reasons – showed no substantial difference suggesting that differential attrition was unlikely, which adds credibility to the results. With the randomized controlled trial design, and with analyses conducted using ITS segmented regression models and DiD GEE showing similar positive results, the evidence for the internal validity of the findings is strong.

Overall success in avoiding missed visits and maintaining women on ARV medications varied widely across all health facilities at both baseline and endline, and responses to the intervention similarly varied across the 12 facilities in the intervention group. Reports from the supervision visits show that how quickly intervention facilities took up the intervention differed markedly and that training in the use of the appointment system alone was not sufficient to change behavior. Many of the intervention facilities took several supervision visits before they had fully implemented the recommended changes. Thus, it appears to require a minimum of four supportive supervision visits to adopt the required changes in clinic practice.

Results showed that not all facilities were successful in reducing rates of missed appointments with urban areas being generally less successful. Qualitative data showed that this was because of a combination of factors; a rapid staff turnover in the larger facilities made any continuity of the intervention difficult; a more transient population made continuity of care for patients more difficult; and a high volume of patients meant that the paper-based system needed the filling in of many pages per clinic day which was difficult to maintain. We decided that for these larger facilities an electronic appointment system is probably more appropriate.

This has consequences for a national scale-up. All facilities (both intervention and control) had been given the appointment books and missing patient registers some months before, as recommended by national HIV and AIDS treatment program policy following our earlier trial in HIV clinics, but they were not using them to their potential at the beginning of the intervention. Mass trainings and dissemination of materials will not be enough to ensure that the system is used correctly.

The intervention required the facility staff to change behavior and systems of care in the clinic, and then to communicate this to patients, whom they only see once a month. The time series figures illustrate that the effect of the intervention increased over time, although we only had a few months after the fourth supervision visit to observe the steady state.

Many interventions introducing new recording systems add to the administrative burden of facility staff and are thus unpopular and often unsuccessful. In this instance, however, clinic staff appreciated the new system because it empowered them to even out their workload and reduce overcrowding in clinics. Patients and staff alike had noted congestion and long waiting times as major problems.

Negotiating with the patient the date and time of her next appointment is a more respectful way of dealing with long-term patients, rather than instructing them to come back on a certain day whether it is convenient for them or not. Before our intervention, half the clinics were doing this, and by the end, all were. This proved popular with both staff and patients and shows an easy first step towards patient-centered services, which

is a concept that was endorsed in May 2016 by the World Health Assembly resolution WHA 69.24 “Strengthening integrated people-centred health services” that supports the “Framework on integrated people-centred health services” (WHO 2015).

Having previously introduced a similar system into specialized AIDS clinics with similar results in Kenya, Rwanda and Tanzania, the evidence for the efficacy of appointment systems and community outreach as a system-level strategy to improve continuity of ART treatment is considerable (Nyamusore et al. 2011; Mwatawala et al. 2012; Boruett et al. 2013). As a result, it is time that policymakers adopted such systems where they are lacking for all ART clinics, be they Option B+ or not. The intervention is inexpensive and the results are convincing. If the MOHSW took on this activity on a wider scale in collaboration with regional health offices and implementation partners in the area, it would be considerably less costly, especially if it was incorporated into routine supervisory activities.

All of the data collected at baseline and endline came from routine clinic records and, therefore, the quality varied in terms of how the information was recorded in medical and pharmacy records. Errors occurred routinely, including incorrect years (especially at the beginning of a new year), transposed dates for the visit and next scheduled visit, the same date used for visit and scheduled date, and reversal of the numbers for day and month in the early part of a month. However, these errors were not differential by study group and therefore did not affect the difference in outcome between intervention and control groups.

In the early implementation of the Option B+ program in RCH clinics, insufficient attention was paid to the consistency and quality of record keeping. Staff in these clinics are familiar with records for maternal healthcare, but the information requirements of an ART program are new and different for them. For the long-term success of the Option B+ program, greater attention must be paid to training staff about the need for and process of reliably collecting and recording data that is essential for HIV treatment and long-term patient management. In addition, the appointment and patient-tracking registers designed for ART clinics were sent out to all Option B+ clinics without adaptation. Many of the volunteers or staff filling in the registers were not comfortable with English. Thus one recommendation is to translate these registers into Kiswahili.

We have shown that by orienting clinic staff in Option B+ RCH clinics and helping them to use the appointment and patient-tracking system, consistent clinic attendance by HIV-positive patients improved. In addition, clinic staff were empowered to be able to plan their schedules, control their workloads, rapidly identify patients who miss appointments, and develop ways to follow up on patients who missed their appointments. As a result of the appointment system and its easy-to-produce summaries, staff could discuss monthly appointment-keeping indicator values as a way of monitoring their progress and engage in continuous quality improvement. This is the first time such improvement has been shown in a non-specialized AIDS clinic.

With chronic diseases becoming ever more prevalent and African healthcare systems having to develop capacity to manage chronic illness more effectively, finding ways to ensure adherence to appointments and therapy is vital. To enable patients to attend at convenient times and minimize their waiting time and to empower clinic staff to know

which patients are expected and rapidly identify non-attenders are fundamental for such care. Lessons learnt from introducing a low-cost appointment and patient-tracking system in a non-specialist RCH clinic treating women on ART are valuable in moving towards a broader chronic illness care model. We now have enough evidence to scale this up to all ART and Option B plus RCH clinics in Tanzania, as well as to test such an intervention in general medical clinics treating other chronic conditions. The steps for implementation of such a system are outlined in Box 1 below and would be effective when dealing with any chronic condition.

Box 1: Key steps to successful implementation of appointment systems

1. Print appointment and patient tracking registers that can allow staff to:
   a. predict and manage clinic workload
   b. rapidly identify those who do not show up, so that patient tracking can be initiated
   c. calculate the monthly percentage of patients who attend the clinic on or within a specified number of days of their appointment as a tool for continuous quality improvement.
   (Tanzanian version is available on request from MSH.)
2. Produce trainers and user manuals to outline how to use the registers and calculate the indicators.
   (Tanzanian version is available on request from MSH.)
3. Train a key group of trainers who can train and supervise clinic staff.
4. Train clinic staff in use of registers and calculation of monthly appointment attendance indicators.
5. Discuss with clinic staff what local resources/community organizations they have locally that they can use or reinforce to follow up missing patients.
6. Encourage clinic staff to hold monthly meetings to review their clinic indicators and discuss how to improve results.
7. Regularly supervise the clinics to reinforce training.

Online Appendices

Note to the reader: Online appendices are provided as received from the authors. These have not been copy-edited or formatted by 3ie.

Online appendix A: Table and screenshots for tablets can be accessed here.
http://www.3ieimpact.org/media/filer_public/2017/07/03/ie59-appendix-a.pdf

Online appendix B: Consent form and interview guidelines can be accessed here.
http://www.3ieimpact.org/media/filer_public/2017/07/03/ie59-appendix-b.pdf

Online appendix C: Report of the qualitative assessments can be accessed here.
http://www.3ieimpact.org/media/filer_public/2017/07/03/ie59-appendix-c.pdf

Online appendix D: STATA figures can be accessed here.
http://www.3ieimpact.org/media/filer_public/2017/07/03/ie59-appendix-d.pdf

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The results demonstrated that a manual system of appointment tracking and subsequent community outreach for patients who miss appointments was low cost and relatively simple to implement. The intervention significantly improved appointment-keeping and consistent availability of antiretroviral medicines in the intervention group compared to the control group for patients on long-term HIV treatment.

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