Pascal Geldsetzer
Joel M Francis
Gerda Asmus
Nzovu Ulenga
Ramya Ambikapathi
David Sando
Wafaie Fawzi
Till Bärnighausen

Impacts of community delivery of antiretroviral drugs in Dar es Salaam, Tanzania

November 2018

Impact Evaluation Report 82

HIV and AIDS

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About this report

3ie accepted the final version of the report, *Impacts of community delivery of antiretroviral drugs in Dar es Salaam, Tanzania*, as partial fulfilment of requirements under grant TW7.13 awarded under the HIV Integration of HIV Services Thematic Window. The content has been copy-edited and formatted for publication by 3ie.

The 3ie technical quality assurance team for this report comprises Anna C Heard, Eric W Djimeu, Emmanuel Jimenez, Annette N Brown, an anonymous external impact evaluation design expert reviewer and an anonymous external sector expert reviewer, with overall technical supervision by Marie Gaarder. The 3ie editorial production team for this report comprises Sahib Singh and Akarsh Gupta, with Beryl Leach providing overall editorial supervision.

 Please direct any comments or queries to the corresponding author, Joel M Francis at joelmfrancis@gmail.com.

Funding for this impact evaluation was provided by 3ie's donors, which include UK Aid, the Bill & Melinda Gates Foundation and the Hewlett Foundation. A complete listing of all of 3ie's donors is available on the 3ie website.

Suggested citation: Francis, JM, Geldsetzer, P, Asmus, G, Ulenga, N, Ambikapathi, R, Sando, D, Fawzi, W and Bärnighausen, T, 2018. *Impacts of community delivery of antiretroviral drugs in Dar es Salaam, Tanzania*, 3ie Impact Evaluation Report 82. New Delhi: International Initiative for Impact Evaluation (3ie). Available at: https://doi.org/10.23846/TW7IE82

Cover photo: Jake Lyell / Alamy Stock Photo.

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Pascal Geldsetzer
Harvard T.H. Chan School of Public Health

Joel M Francis
Management and Development for Health
Harvard T.H. Chan School of Public Health

Gerda Asmus
University of Heidelberg

Nzovu Ulenga
Management and Development for Health

Ramya Ambikapathi
Harvard T.H. Chan School of Public Health

David Sando
Harvard T.H. Chan School of Public Health

Wafaie Fawzi
Harvard T.H. Chan School of Public Health

Till Bärnighausen
University of Heidelberg
Harvard T.H. Chan School of Public Health
Africa Health Research Institute

3ie Impact Evaluation Report 82

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Acknowledgements

We would like to thank all study participants for their time and willingness to participate in this study, the data collection team, the home-based carers who delivered most components of the intervention, and the administrative staff at both the Harvard T.H. Chan School of Public Health, as well as Management and Development for Health. Importantly, we would also like to extend our sincere gratitude to the health facility management, municipality health management, and Tanzania's National AIDS Control Programme for their support with this trial. Lastly, we are grateful for funding from the International Initiative for Impact Evaluation (3ie), as well as the support from 3ie staff, particularly Dr. Anna Heard and Ms. Nancy Diaz.

Parts of the introduction and background section in this report can be found in our detailed study protocol publication published in *BMC Health Services Research* (Geldsetzer et al. 2017).

Abstract

Background

With the increase in people living with HIV in sub-Saharan Africa and expanding eligibility criteria for antiretroviral therapy (ART), there is intense interest among policymakers in the use of 'differentiated' care delivery models that can allow under-staffed health systems in the region to deal with an increasing demand for ART care. Differentiated ART care provides varying intensities and modalities of care to ART patients based on their clinical need.

One such model is community delivery of antiretroviral drugs (ARVs) through community health workers (CHWs), which has the potential to reduce patients' healthcare expenditures and decongest healthcare facilities. Set in Dar es Salaam, Tanzania, this pragmatic randomized trial aims to assess whether a differentiated ART care model (CHW-led ARV community delivery for those who are stable on ART and standard facility-based care for those who are unstable) results in a non-inferior probability of viral failure compared to the standard of care (standard facility-based care for all ART patients).

Methods

The study took place from March 2016 through October 2017. All (48) healthcare facilities in Dar es Salaam that provided ART care and had an affiliated team of public sector CHWs were randomized to either the differentiated ART care model or standard facility-based care. The trial offered enrolment to all ART patients residing in the facility's catchment area. Clinical stability on ART was defined as: (1) taking ARVs for at least six months; (2) having had a CD4-cell count > 350 cells/μl or a suppressed viral load (VL) at six or more months after ART initiation; and (3) the most current VL having been taken less than 12 months prior to study enrolment and showing viral suppression. The primary endpoint was the proportion of ART patients in viral failure (VL > 1,000 copies/ml) at the end of the study period. The margin of non-inferiority was set in the study protocol at a risk ratio (RR) of 1.45. The mean follow-up period was 326 days. We obtained RRs using a log-binomial model, adjusting standard errors for clustering at the level of the healthcare facility.

Results

In total, 1,163 and 1,009 participants were enrolled at intervention and control facilities, respectively; 516 received CHW-led ARV community delivery. 18.9% of participants in intervention and 13.6% in control facilities were lost to follow-up. The RR for viral failure in the intervention compared to the control arm was 0.89, with the upper bound of a one-sided 95 per cent confidence interval (CI) being 1.18. We observed no significant difference in participants' healthcare expenditures over the past six months between intervention and control facilities. The total cost of the intervention was TZS 197,900,500 (USD 286,227). The percentage of all ART patients at each intervention facility who received ARV community delivery varied from 0.3% to 19.0%, with an (unweighted) mean of 4.4%. 97.2% (95% CI: 94.7–98.7) of those who received ARV community delivery reported to be either "satisfied" or "very satisfied" with the program.

Discussion

The differentiated ART care model appears to have led to non-inferior health outcomes (as assessed through the risk of viral failure) but did not significantly reduce participants' healthcare expenditures. Satisfaction with the program was high and will likely save ART patients substantial amounts of time. A major limitation is that only a small proportion of ART care patients at a healthcare facility could be enrolled in the program due to the restriction that participants must reside in the healthcare facility's catchment area to be eligible for ARV community delivery. Local policymakers may consider piloting and evaluating a more ambitious ARV community delivery program that can reach a higher proportion of ART care patients in Dar es Salaam.

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Abbreviations

ART	Antiretroviral therapy
ARV	Antiretroviral drug
CD4	Cluster of differentiation 4
CHW	Community health worker
CI	Confidence interval
HBC	Home-based carer
ICC	Intra-cluster correlation coefficient
IQR	Interquartile range
LMICs	Low- and middle-income countries
MDH	Management and Development for Health
PMTCT	Prevention of mother-to-child HIV transmission
PPP	Purchasing power parity
RR	Risk ratio
SD	Standard deviation
SSA	Sub-Saharan Africa
TZS	Tanzanian Shillings
USD	US dollars
µl	Microliter
ml	Milliliter
VL	Viral load
WHO	World Health Organization

1. Introduction

An estimated 37 per cent of the 24.7 million people living with HIV in Sub-Saharan Africa (SSA) were receiving antiretroviral therapy (ART) in 2015 (WHO 2015; UNAIDS 2015; Geldsetzer et al. 2017). Since the advent of antiretroviral drugs (ARVs), the World Health Organization (WHO) has gradually increased the recommended treatment threshold from a CD4-cell count of less than 200 cells/µl in 2006 (WHO 2006), to less than 350 cells/µl in 2010 (WHO 2010), and less than 500 cells/µl in 2013 (WHO 2013). Most recently, in 2015, WHO eliminated any CD4-cell count treatment threshold, recommending ART for all people living with HIV (WHO 2016). As ART patients live into old age and countries expand ART eligibility, this will likely lead to a substantial rise in the number of people on ART in SSA in the coming years (WHO 2016). This calls for new models of care that allow health systems to deal with a higher number of ART patients without reducing quality of care.

1.1 The importance of ART adherence

The benefits from the scale-up in ART coverage will critically depend on lifelong adherence to ART. A meta-analysis pooling ART adherence data from over 30,000 adult patients in 84 observational studies across 20 countries found that 38 per cent of patients took less than 90 per cent of prescribed ART doses (Ortego et al. 2011). Similarly, previous analyses by our team in a cohort of over 44,000 patients in Dar es Salaam's adult HIV treatment and care program found low retention in ART care and low adherence. More specifically, we found that 39 per cent of adults on ART were lost to follow-up within 12 months of initiation (unpublished data). In addition, 19 per cent were non-adherent to ART (Muya et al. 2014) (as defined by non-compliance with scheduled ART pickup visits of greater than 5%) at any given point in time, with the risk of non-adherence increasing with duration on ART. Worryingly, the risk of non-adherence also rose independently with increasing calendar year, with the relative risk (RR) of non-adherence being 2.01 (95% CI: 1.93–2.10) in 2010 compared to 2004. Poor adherence is not only likely to lead to treatment failure and resulting morbidity and mortality, but also increases the risk of HIV transmission and, crucially, the development of resistant HIV strains (Press et al. 2002; Wood et al. 2003; Bangsberg et al. 2001). Increasing ART resistance may narrow future ARV drug options, thereby reducing ART access and increasing the cost of effective HIV treatment as programs have to move to more expensive second- and third-line regimens.

1.2 Why community delivery to improve ART adherence?

In a large qualitative study in three urban settings in SSA, including Dar es Salaam, Ware et al. (2013) found that the main unintentional reason for missed ART clinic visits was lack of time due to other, often unexpected, events in a patient's life. In addition, many studies have identified the cost to patients of attending ART clinics as being important barriers to retention in ART care; not just expenses in relation to user fees but also transport, food and lost income (Ware et al. 2013; Tuller et al. 2010; Hardon et al. 2007; Meyer-Rath 2007; Tomori et al. 2014); transport-related factors (Lankowski et al. 2014); and long clinic waiting times (Ware et al., 2013). Given that delivery of ARVs to homes through community health workers (CHWs) would overcome many of these barriers, CHWs have the potential to significantly improve ART retention and adherence.

An additional possible benefit of this community-based approach arises from the resulting reduced patient load at ART clinics, which may decrease waiting times and improve quality of care as facility-based healthcare workers have more time available per patient. The community delivery of ARVs by CHWs is, therefore, not merely an intervention aimed at improving ART adherence but also a measure that can shift care from more highly trained to less well-trained health workers.

Such task-shifting measures may therefore alleviate the severe shortage of human resources for health in SSA, which is a central barrier to attaining universal coverage of HIV services (Barnighausen et al. 2007; Wouters et al. 2009). WHO has identified 313 tasks that are essential for the prevention of HIV transmission, identification of HIV-infected individuals, provision of basic HIV-related clinical management, and initiation and maintenance of patients on ART. WHO recommends that 115 of these tasks, including dispensing ARVs, can be performed by CHWs, highlighting the immense potential of task-shifting for HIV-related care (WHO 2008).

1.2.1 The current evidence base for community delivery of ARVs by CHWs

A systematic review of health service delivery for ART provision identified two randomized trials that evaluated ARV community delivery programs (Lazarus et al. 2014). Both trials randomized geographical areas around one ART clinic. The first trial was set in rural Uganda and randomized areas to either community delivery of ARVs by field officers or standard facility-based ART care (Jaffar et al. 2009). The participants were patients newly initiated on ART.

The trial found no difference between study arms in the rate of viral failure or mortality, either after six months (Jaffar et al. 2009) or at 36-month follow-up (Amuron et al. 2011). The median expense to patients in terms of transport costs, food, child care and lost work time due to ART care was higher in the facility-based group than in the home-based group, at USD 60 versus USD 29 in the first year and USD 54 versus USD 18 in subsequent years. In addition, the median cost to the health system per patient per year was somewhat lower in the CHW group (USD 793) than in the facility-based group (USD 838), as the increased transport costs for CHWs were offset by patients' reduced clinic attendance.

In a separate study, the same cohort of patients receiving ARVs, community delivery was compared with ART patients who attended a physician-staffed hospital in an urban sub-municipality of Uganda (Kipp et al. 2011, Kipp et al. 2012). While comparability of the two cohorts is limited by the observational study design, the study found that community-based participants were more likely to achieve viral suppression (after adjusting for CD4-count at baseline and socio-demographic characteristics); there was no difference in all-cause mortality.

The second randomized trial was carried out in rural Kenya and, similar to the Uganda study, found no difference in the percentage of patients with an undetectable VL; mean CD4-count; incidence of opportunistic infections; and change in ART regimen between stable ART patients who received ARVs from CHWs during home visits, compared to patients randomized to standard facility-based ART care (Selke et al. 2010).

This trial differs in several crucial aspects from the two studies described above. Firstly, this is the first trial to evaluate ARV community delivery in an urban setting. Secondly, this is a health systems trial, which implements the intervention directly into the routine healthcare system. Both the Uganda and Kenya trials randomized geographic areas around one clinic run by a non-governmental organization (Jaffar et al. 2009, Selke et al. 2010); whereas this study was implemented at all healthcare facilities of Dar es Salaam that offer ART care and have an affiliated team of public sector CHWs (with the exception of two facilities).

In addition, while the Uganda trial trained field officers to deliver ARVs by motorbike and the Kenya trial trained ART patients at the clinic to act as community care coordinators, this trial utilizes a large existing public sector CHW program in Dar es Salaam called home-based carers (HBCs). Thirdly, this trial includes 24 healthcare facilities in each study arm, whereas both the Uganda and Kenya trials implemented the intervention at only one clinic.

Aside from external validity concerns, an important disadvantage of drawing the intervention and control groups from the same healthcare facility is that ARV community delivery is likely to have affected the care provided to the control group, as the shifting of patients to community-based care substantially reduced the patient volume at the facility. This may have resulted in the control group being a poor counterfactual.

1.3 Objectives of the study

This non-inferiority pragmatic cluster-randomized trial evaluates the feasibility and effectiveness of HBC-led community delivery of ARVs in the routine healthcare system of Dar es Salaam. More specifically, this study aims to determine whether a differentiated ART care model (ARV community delivery for patients who are clinically stable on ART and standard facility-based care for those who are not stable on ART) is non-inferior to the standard of care (facility-based care for all ART patients) in preventing and treating viral failure. A secondary aim of this study is to assess the impact of the differentiated ART care model on patients' healthcare expenditures.

2. Background/context

2.1 Study setting

The study was implemented in all three municipalities of the Dar es Salaam region of Tanzania (Temeke, Kinondoni and Ilala), which also contains the city of Dar es Salaam (Geldsetzer et al. 2017). Dar es Salaam had a population of 4.4 million inhabitants in 2012 (National Bureau of Statistics and Office of Chief Government Statistician 2012). The average household size in Dar es Salaam region was 4.0 people and virtually the same across its three municipalities (ranging from 3.9 to 4.0). Dar es Salaam's HIV prevalence was 6.9 per cent among adults aged 15–49 years in 2012, which was above the national prevalence of 5.1 per cent (Tanzania Commission for AIDS et al. 2013).

This trial utilized an existing and long-standing public sector CHW cadre, known as HBCs, to deliver the intervention. The HBCs are employed by Dar es Salaam's municipalities and receive a stipend of TZS 50,000, approximately equal to USD 23, unadjusted for purchasing power parity (PPP) over the duration of the study period. As

part of this trial, HBCs in the intervention arm received a further TZS 75,000 flat payment per month to compensate them for additional transport costs and workload. Because HBCs had a varying number of ARV community delivery clients, this payment was changed to a payment of TZS 10,000 per community ARV delivery visit in January 2017.

HBCs are lay healthcare workers whose main responsibility is to conduct regular home visits (at least once every three months) to HIV patients in the neighborhood to which they have been assigned. The precise tasks of the HBCs during these home visits have varied somewhat over the years, but generally consist of the provision of information on family planning and HIV-related counseling services. The HBC program exists in most, but not all, areas of Dar es Salaam. In those areas where the HBC program has been implemented, each neighborhood has 1–3 HBCs, who are residents of the neighborhoods to which they have been assigned.

2.2 The intervention

In clusters randomized to ARV community delivery, an HBC visited participants at home to provide counseling, deliver a supply of ARVs and perform an ARV pill count. In the study exit questionnaire, 30.8 per cent (106/355) of participants who had received ARV community delivery reported usually receiving their ARVs from the HBC at a location other than their household, such as their workplace.

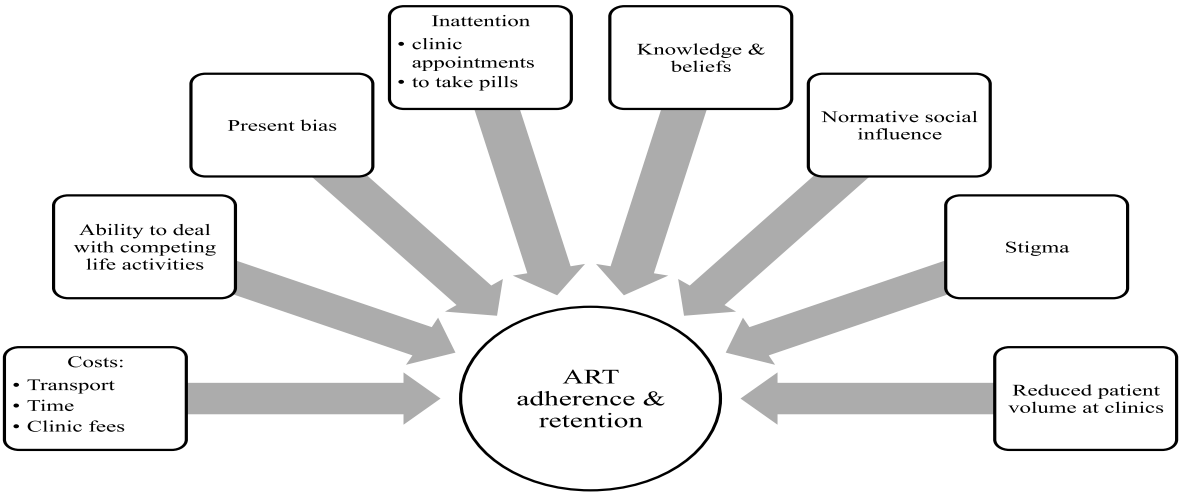
We maintained participants' usual facility ART schedule in the ARV community delivery intervention, which was either a monthly or two-monthly HIV care visit. For instance, an ART patient who was scheduled to visit the facility every two months, and was provided with a two-month ARV supply, received an HBC visit for ARV community delivery every two months, and received a two-month ARV supply from the HBC.

On paper, patients in the intervention arm only had to attend the healthcare facility every 12 months for a clinical check-up. In this study, however, the next visit (after eligibility for ARV community delivery was fully assessed) to the facility for ART care by patients in the intervention arm was for the study exit assessment. HBCs in the intervention arm received three days of training on community delivery of ARVs and counseling skills for this intervention prior to the start of the trial. Counseling focused on ART adherence, family planning, prevention of onward HIV transmission and basic nutrition.

2.3 Theory of change

Figure 1 depicts the possible mechanisms through which the intervention could affect ART adherence and retention and thus VL.

Figure 1: Mechanisms through which ARV community delivery may affect ART adherence and retention



2.3.1 Costs

A study in KwaZulu-Natal, South Africa, has shown that despite ARVs being free of charge, out-of-pocket costs to ART patients are substantial, mostly due to transport costs and time lost from work (Chimbindi et al. 2015). By reducing the number of times that ART patients have to travel to the clinic, ARV community delivery has the potential to substantially reduce patients' out-of-pocket expenditures for ART care and thus improve retention in care.

2.3.2 Ability to deal with competing life activities

Qualitative evidence suggests that an important reason for unintentionally missing ART clinic visits is competing unexpected demands on patients' time, such as weddings and funerals (Ware et al. 2013). ARV community delivery reduces the demand on patients' time to receive ART and may thus increase their ability to deal with competing life activities without having to miss their ART care appointments.

2.3.3 Present bias

Having to attend ART care is an activity that is vulnerable to present bias or, in other words, procrastination, given that ART care visits are both costly (in terms of time and money) and, plausibly, also unpleasant for patients (for example, due to stigma). Patients may therefore repeatedly delay attending the ART clinic. Once they have been out of care for several weeks, patients may feel too ashamed to return to care for fear of 'scolding' by facility-based healthcare workers (Ware et al. 2013).

Present bias may thus be an important reason for non-retention in ART care. By placing the initiative for the ART visit on the HBC rather than the patient, ARV community delivery can plausibly reduce this present bias and thus increase the proportion of patients who remain in ART care.

2.3.4 Attention

Patients may forget to attend their clinic appointments and/or to take their medications. There is strong evidence that inattention, or forgetting, is an important reason for ART non-adherence. For instance, phone-based reminders, in the form of calls or text messages repeatedly have been shown to be effective in increasing ART adherence in

the short term. More research is needed to determine whether phone-based reminders are also effective in the longer term (Chaiyachati et al. 2014). ARV community delivery largely removes the need for patients to remember their clinic appointments. In addition, as HBCs work in the communities in which they live, HBCs and their patients may frequently see each other in the community, which might serve as a passive reminder for patients to take their ARVs.

2.3.5 Knowledge and beliefs

HBCs are trained in, and tasked to provide counseling on, HIV and ART during home visits. This counseling may alter patients' knowledge and beliefs. For instance, as laid out in the health belief model (Janz and Becker 1984), knowledge and beliefs around ART and HIV may affect medication adherence and care retention by, for example, changing perceived benefits of taking ART and remaining in ART care.

Whether ARV community delivery is an improvement or deterioration in this regard, compared with facility-based care, is unclear, as facility-based healthcare workers may also provide relevant counseling. The effect here will depend on a variety of factors, such as trust in the CHW versus the facility-based healthcare worker, their relative likelihood of providing counseling and the quality of their counseling.

2.3.6 Normative social influence

Participants are likely to perceive good ART adherence as a socially desirable norm for an ART patient. HBCs will re-emphasize this norm through their counseling during home visits. In addition, HBCs will verify whether patients are meeting this norm through informal questioning during home visits and pill counts. ARV community delivery may thus increase ART adherence through the normative social influence the HBCs exert.

2.3.7 Stigma

It is difficult to predict how ARV community delivery will affect ART adherence and retention through altering stigma. On the one hand, not having to attend a nearby ART clinic, which often has a separate waiting room for patients living with HIV, may reduce stigma. On the other, HBC-led household visits may lead to unintentional disclosure of the patients' HIV status to other household members and possibly also community members (for example, if the HBC does not maintain confidentiality or because community members find out what the HBC's tasks are). However, as patients in this study can opt to continue with facility-based rather than HBC-led HIV care, it is plausible that patients will select the care option that they perceive as being less stigmatizing, which may in turn result in increased ART retention.

2.3.8 Reduced patient volume at clinics

Reducing the frequency with which patients have to attend ART care may result in lower patient numbers at HIV clinics. This in turn may lead to reduced patient waiting times and increased perceived quality of care (for example, because healthcare workers have more time available to spend with patients) for patients who are either ineligible for, or did not opt into, ARV community delivery. Both reduced waiting times and increased perceived quality of care could plausibly lead to increased ART adherence and retention.

2.4 Study duration

Enrolment into the trial took place in healthcare facilities in Temeke municipality from March 1, 2016 to July 29, 2016. Because the number of participants enrolled in Temeke was lower than expected, the trial was expanded to 16 healthcare facilities in Kinondoni municipality and 14 healthcare facilities in Ilala municipality. Enrolment in Kinondoni took place from August 1, 2016 through October 31, 2016; and in Ilala from November 1, 2016 through January 31, 2017. Study exit assessments started in Temeke in March 2017, in Kinondoni in May 2017 and in Ilala in June 2017. The study activities during the trial period are detailed in Appendix 1.

2.4.1 Endpoints

The primary endpoint for this trial was the proportion of enrolled patients in viral failure at the end of the study period. The secondary endpoint was participants' healthcare expenditures in the past six months.

2.5 Obstacles for implementation

The number of participants eligible for enrolment into the trial was lower than had been expected at the time of designing this study. The main reason was that fewer participants than expected resided in the catchment area of the facility (in other words, were reachable by the HBCs affiliated with the healthcare facility in question) and were thus eligible for enrolment into the trial. This was an important limitation of the intervention design as it resulted in only 2,172 participants being enrolled into this trial out of 71,168 ART patients at the healthcare facilities in this study.

The decision to enroll only participants residing in the catchment area of the facility was made because removing this condition would have meant that healthcare facilities and HBCs would have needed to communicate with each other to organize ARV community delivery across the entire city; or HBCs would have needed to travel across the entire city, which would have been costly and time-consuming. This was deemed logistically infeasible at the time of designing the study, but a more detailed elaboration on this issue is provided in the discussion.

A second important obstacle faced during enrolment was that many participants did not have a VL or CD4-cell count taken in the 12 months prior to enrolment. In consequence, a blood sample for VL testing had to be taken at enrolment, sent to the public sector healthcare system's laboratory and the results awaited. In most cases, there was a delay of 2–4 weeks (and up to 12 weeks in some cases) between sending the blood sample and receiving the results, and thus a delay in assessing patients' eligibility for ARV community delivery.

3. Data and methods

3.1 Ethics

The study was approved by the research ethics committee of the National Institutes of Medical Research in Tanzania on July 16, 2015 and received an exemption from the institutional review board of the Harvard T.H. Chan School of Public Health in June 2015.

3.2 Margin of non-inferiority

The non-inferiority design only applies to the primary endpoint (the proportion of participants in viral failure) (Geldsetzer et al. 2017). This design choice was made because in settings with an existing HBC program, such as in Dar es Salaam, HBC-led community delivery should likely be the standard of care if it does not negatively affect patients' health outcomes as compared to standard facility-based care. Two envisaged benefits of HBC-led ARV community delivery are a reduction in: (1) patient volume at healthcare facilities, which helps to alleviate the severe shortage of skilled healthcare workers in SSA (Bärnighausen et al. 2007); and (2) the substantial time and financial burden (for example, transport costs) on patients of having to attend an ART facility (Chimbindi et al. 2015; Jaffar et al. 2009).

The main drawbacks of HBC-led ARV community delivery are the cost of establishing and running the HBC program; and the risk of overburdening HBCs, which may lead to a reduction in quality and/or quantity of care for non-ART patients. We would argue that in the case of Dar es Salaam, the cost consideration is minor as the HBC program already exists and HBCs are supposed to visit HIV patients on a regular basis. Similarly, since the main time burden on HBCs is to travel or walk to households, rather than the visit itself, the additional task of handing over ARVs to the client is minor.

Based on consultations with Tanzania's National AIDS Control Programme, and in line with the margin of equivalence used by (Jaffar et al. 2009) in their randomized trial of ARV home delivery in rural Uganda, we chose a margin of non-inferiority for the RR of viral failure of 1.45. That is, if the RR of viral failure in the intervention group compared to the control group is statistically significantly lower than 1.45, then ARV community delivery is considered to be non-inferior to standard facility-based care. On an absolute scale, this non-inferiority margin corresponds to a higher absolute probability of viral failure in the intervention group of nine percentage points, assuming (as done by Jaffar et al. (2009)) that 20 per cent of participants in the control arm of the study are in viral failure at the end of the follow-up period.

3.3 Power

We expected to recruit approximately 1,000 participants in each of the two trial arms (2,000 participants in total). We calculated the design effect (taking into account clustering of outcomes at the facility level and varying cluster sizes) for this trial using the 'clustersampsi' function in Stata (Hemming and Marsh 2013). The design effect was then used to adjust the expected power calculated for a non-inferiority trial under individual randomization, which we determined using the 'ssi' function in Stata (Jones 2010). Our calculations assumed that 20 per cent of enrolled participants would be in viral failure at baseline. The margin of non-inferiority was set at an RR of 1.45.

We used a range of intra-cluster correlation coefficients (ICCs) from 0.005 to 0.020. Barnhart et al. (2016) calculated ICC values for CD4-cell count measures in Dar es Salaam. The six-month cumulative incidence for non-adherence to ARVs (defined as a 50 per cent drop in CD4-count from its peak value and return to pre-ART CD4-count or lower after 168 days on ART or a VL greater than 10,000 after 168 days on ART) had an ICC value of 0.016 (95% CI: 0.009–0.029). We set the probability of a type one statistical

error at 0.05 and assumed a correlation coefficient between baseline and study exit VL measurement of 0.5. We found that we were well powered (≥ 80% power) to detect modest one-sided differences in the proportion of participants who were in viral failure between the two study arms.

3.4 Randomization

The unit of randomization was a healthcare facility with its surrounding catchment area. Which healthcare facilities were included in this study was determined by the supervisory structure of HBCs in the routine public sector health system. Each HBC is supervised by one community outreach nurse who is a nurse based at a healthcare facility. Each community outreach nurse supervises between 3 and 12 HBCs who work in neighborhoods (*mtaa* in Kiswahili) in the facility's catchment area. In all municipalities of Dar es Salaam, we included all healthcare facilities in this trial that provided ART care and had a community outreach nurse (and thus a team of affiliated HBCs) at the time of the study start date. Table 1 details the characteristics of each cluster.

Table 1: Characteristics of the clusters

Name of healthcare facility	Type of healthcare facility	Municipality	No. of patients currently on ART	No. of HBCs in cluster
ARV community delivery				
1. Mbagala Rangi Tatu	Hospital	Temeke	15,663	3
2. Tambukareli	Dispensary	Temeke	1,554	12
3. Yombo Makangarawe	Dispensary	Temeke	544	2
4. Toa Ngoma	Dispensary	Temeke	239	12
5. Buza	Dispensary	Temeke	215	5
6. Arafa Ugweno	Dispensary	Temeke	202	3
7. Mji mwema	Dispensary	Temeke	161	8
8. Kimbiji	Dispensary	Temeke	119	6
9. Keko	Dispensary	Temeke	79	4
10. Tandale	Dispensary	Kinondoni	2,951	9
11. Mburahati	Dispensary	Kinondoni	1,639	11
12. Mwenge	Dispensary	Kinondoni	1,597	5
13. Mbezi	Dispensary	Kinondoni	870	11
14. Hananasif	Dispensary	Kinondoni	530	7
15. Kigogo	Dispensary	Kinondoni	347	3
16. Mabibo	Dispensary	Kinondoni	278	9
17. Goba	Dispensary	Kinondoni	177	4
18. Tabata	Health Centre	Ilala	2,193	10
19. Vingunguti	Health Centre	Ilala	1,865	7
20. Kitunda	Health Centre	Ilala	768	10
21. Pugu Kajiungeni	Dispensary	Ilala	561	11
22. Tabata NBC	Dispensary	Ilala	249	10
23. Kinyerezi	Dispensary	Ilala	238	13
24. Mongolandege	Dispensary	Ilala	152	16

Name of healthcare facility	Type of healthcare facility	Municipality	No. of patients currently on ART	No. of HBCs in cluster
	Total:		***33,191[1]***	***191***
Standard of care				
1. Temeke	Hospital	Temeke	17,409	3
2. Kigamboni	Health Centre	Temeke	2,879	9
3. Mbagala Round Table	Dispensary	Temeke	850	5
4. Maji Matitu	Dispensary	Temeke	540	7
5. Kichemchem	Dispensary	Temeke	211	3
6. Kingugi	Dispensary	Temeke	166	6
7. Sandali	Dispensary	Temeke	148	9
8. Kibada	Dispensary	Temeke	109	8
9. Kisarawe II	Dispensary	Temeke	63	5
10. Magomeni	Health Center	Kinondoni	2,361	8
11. Kimara	Dispensary	Kinondoni	2,270	5
12. Bunju	Dispensary	Kinondoni	1,595	7
13. Kawe	Dispensary	Kinondoni	844	5
14. Kijitonyama	Dispensary	Kinondoni	750	8
15. Kinondoni	Hospital	Kinondoni	396	5
16. Makuburi	Dispensary	Kinondoni	256	4
17. Ununio	Dispensary	Kinondoni	115	6
18. Mnazi Mmoja Health Centre	Health Centre	Ilala	3,650	4
19. Chanika	Health Centre	Ilala	1,413	12
20. Segerea	Health Centre	Ilala	678	8
21. Kiwalani	Dispensary	Ilala	519	13
22. Gerezani	Dispensary	Ilala	350	2
23. Majohe	Dispensary	Ilala	220	10
24. Mvuti	Dispensary	Ilala	185	16
	Total:		***37,977[1]***	***168***

[1]This is *not* the expected number of participants as many ART patients did not reside in the cluster (in other words, in the area surrounding the healthcare facility) and were therefore not eligible for this trial.

Acknowledgement: This table has been adapted from Geldsetzer et al. (2017).

For the purposes of randomization, clusters were first matched into pairs, separately within each municipality, based on the number of patients currently on ART at the facility. More specifically, the facility with the highest number of ART patients in Temeke was paired with the facility with the second-highest number of ART patients in Temeke and so on. The rationale for this choice was that the intervention would become more complex to implement (and would thus have affect the primary endpoint) with an increasing volume of eligible participants.

Each healthcare facility only had one community outreach nurse (apart from Kigamboni Health Centre and Mbezi Dispensary, which had two). Thus, with an increasing number of eligible participants (for which ART patient volume is a proxy), the number of patients for whom the community outreach nurse had to supervise ARV community delivery

increased. An added benefit of matching on size prior to randomization was that it ensured an approximately equal number of participants in each study arm, which maximized statistical power. The randomization was conducted prior to the start of the study using computer-generated random numbers. For feasibility reasons, neither the research team nor the study participants were blinded to the intervention assignment.

3.5 Recruitment

One or two study team members (henceforth referred to as data collectors) were placed full-time at each of the participating healthcare facilities for the duration of the periods for enrolment and the study exit assessment. During the follow-up period, most data collectors split their time between three facilities (one in each municipality). The ART nurse at each of the participating healthcare facilities sent all ART patients who lived in the facility's catchment area to the data collector. The data collector then introduced the study to the patients and, provided the patient gave initial verbal consent, ascertained whether they were (1) stable on ART (see eligibility criteria); and (2) resided in the facility's catchment area.

If both criteria were fulfilled, the data collector conducted the written informed consent procedure and administered a tablet-based baseline questionnaire. In addition, for participants who did not have a VL measurement in the 12 months prior to study enrolment, the data collector referred the client to the provider (usually a nurse) who took a blood sample that was sent for an HIV VL. Lastly, the data collector took a map cue (a description of the location of the participant's residence) from participants and recorded their cellphone number as well as the cellphone number from at least one household member. The HBC supervisor at the facility gave the details to the HBC assigned to the neighborhood in which the participant lived.

3.6 Eligibility criteria

The eligibility criteria for participants in this trial were: (1) being aged 18 years or older; (2) attending one of the participating healthcare facilities for ART care during the enrolment period; and (3) residing in a neighborhood in the facility's catchment area. An additional eligibility criterion for ARV community delivery was being clinically stable on ART. Based on discussions with Tanzania's National AIDS Control Programme, patients were clinically stable on ART if their most recent VL had been taken less than 12 months prior to enrolment and showed viral suppression.

If a VL measurement was unavailable at the time of enrolment but a CD4-cell count taken in the 12 months prior to enrolment was available, then patients were clinically stable on ART if the most current CD4-cell count was > 350 cells/µl. If neither a VL nor a CD4-count taken in the 12 months prior to enrolment were available, then a venous blood sample was taken for a VL measurement and the result used for the eligibility assessment.

Additional requirements for being stable on ART were: (1) taking ARVs for at least six months; and (2) having had a CD4-cell count > 350 cells/µl or a suppressed VL at six or more months after ART initiation. Patients who were pregnant at the time of enrolment (by patient self-report) or unable to provide written informed consent (for example, due to mental incapacity) were excluded.

3.7 Data collection

This trial was implemented by Management and Development for Health (MDH). MDH is a Tanzanian non-governmental organization based in Dar es Salaam that works closely with Tanzania's Ministry of Health and Social Welfare. MDH worked on this trial in partnership with the Harvard T.H. Chan School of Public Health, which provided technical assistance throughout the study period.

3.7.1 Biomarkers

HIV VL was measured at baseline and at the end of the study period. If a participant had a VL measurement in the 12 months prior to study enrolment, this measurement was used as the baseline VL. The VL measurements were conducted at Temeke laboratory using Cobas Ampliprep-Taqman 96 and Cobas 4800 analyzers.

3.7.2 Questionnaires

The study's team of trained data collectors administered a tablet-based questionnaire at enrolment ("baseline questionnaire"), and then again at the end of the study period ("study exit questionnaire"). This questionnaire asked about basic socio-demographic information, health service utilization, out-of-pocket healthcare expenditures and satisfaction with HBC services.

Regarding health service utilization and healthcare expenditures, participants were asked about the cost they had incurred to attend the ART care visit on the day of the interview. Specifically, participants were asked about costs they had incurred for each of the following: consultation fees; medical tests; medicines; transport; payment for someone to look after their children while they were gone; food; phone calls and SMS; and income lost due to the time spent to attend the healthcare facility.

In addition, participants were asked about the costs they had incurred for primary healthcare visits during the past six months to each of the following types of providers: public primary care clinic; private doctor; chemist/pharmacy; traditional healer; diviner; and faith healer. For each of these types of providers, participants were asked how much they spent on: consultation fees; medical tests; medicines; transport; payment for someone to look after their children while they were gone; food; and phone calls and SMS. But they were not asked about income lost due to the time spent to attend the healthcare facility.

3.7.3 Qualitative data collection

At the end of the study period, data collectors trained in qualitative interviewing conducted semi-structured qualitative interviews with a purposive sample of community outreach nurses, HBCs and participants in the ARV community delivery arm. Participants were selected to represent a variety of healthcare facilities and age groups. These interviews aimed to ascertain healthcare workers' and participants' experiences with ARV community delivery; and their suggestions for improvement in the delivery of the intervention.

The qualitative study was conducted from August 2017 through October 2017 and included 44 semi-structured qualitative interviews. Among these interviews, 20 were from the participants who participated in the ARV community delivery program, 20 from HBCs, and 4 from HBC supervisors (a facility-based nurse). The interviews lasted between 60

and 90 minutes. They were conducted by two qualitative research assistants who were familiar with the trial and took place either in clinics (in the case of HBCs) or in a private residence (in the case of participants enrolled in the study).

The language for all interviews was Kiswahili. Interviews were transcribed and translated into English. Among the 20 participants, 11 were women, with a mean age of 40 years; the male participants were typically older, with a mean age of 46 years. Some 55 per cent of the HBCs were women aged between 40 and 49 years. In addition, during the first three months of the study period, semi-structured qualitative interviews were conducted with eight patients who were offered ARV community delivery, but refused to enroll in ARV community delivery, to identify their reasoning for preferring facility-based ART care.

3.7.4 Challenges with data collection

We experienced three major challenges during data collection. Firstly, most participants did not have a VL or CD4-cell count taken in the preceding 12 months in their clinical records at the time of the baseline questionnaire, so the study team had to send a blood sample for VL testing to the laboratory. Receiving the results from the laboratory on these VL measurements took between 4 and 12 weeks. Thus, for most participants, the study team was not able to assess eligibility for the intervention until 1–3 months after the baseline questionnaire administration. The timeline of the trial was extended to adjust for this delay.

Secondly, 417 participants did not return to the facility for their study exit assessment (and a clinical check-up); 136 of these participants were at control facilities and 281 at intervention facilities. For some of these individuals, as well as many individuals who had missing VL results for other reasons, we were able to retrieve their latest VL from the central health system database kept at MDH. This database records all VLs taken at any healthcare facility in Dar es Salaam.

Thirdly, we experienced difficulties in linking participants across our different study databases. The databases used in this study were a study logbook, in which the data collection team kept a list of all participants in the trial, including their age and sex; the baseline questionnaire data; baseline laboratory data; and study exit questionnaire data.

Out of the 2,172 participants in this study, we had all questionnaire data for 1,348 participants; 193 had only logbook data; 94 only logbook and baseline questionnaire data; 139 only logbook and baseline laboratory questionnaire data; 271 only logbook, baseline questionnaire and baseline laboratory questionnaire data; and 127 only logbook and endline questionnaire data. The proportion with complete data was similar between the two study arms: 64.7 per cent in the control arm and 59.6 per cent in the intervention arm. These matching issues were responsible for the relatively high level of missingness in socio-demographic variables other than age and sex; and the lower sample size for the analysis of healthcare expenditures as compared to VL measurements.

In addition to a relatively high number of people not returning to the healthcare facility for the study exit assessment (see above), the main cause of unsuccessful matches was that data collection officers entered neither the health system patient identifying number correctly into the tablet nor the study identifying number. While those lost to follow-up

may well be systematically different to those not lost to follow-up, it appears unlikely that those for whom the data collector entered the identifying numbers incorrectly into the tablet would be systematically different to those for whom these numbers were entered correctly.

3.8 Statistical analysis

The primary analysis in this study is an intent-to-treat analysis. We consider all participants at a healthcare facility to be in the intent-to-treat sample (regardless of whether they were stable on ART and thus eligible for ARV community delivery) because shifting patients from facility- to community-based care could have an impact on the care received by those remaining in standard facility-based care at intervention facilities. However, in secondary analyses, we also examine the treatment effects among only those who had a suppressed VL, or if no VL measurement is available, a CD4-cell count > 350 cells/µl, at baseline (henceforth the two combined are simply referred to as 'suppressed VL at baseline' for simplicity).

In addition, we estimate the complier average causal effect (in other words, the effect of the intervention on those who received the intervention) using an instrumental variable analysis. The complier average causal effect is estimated using an ordinary least squares regression model, with randomization to an intervention facility being the instrument and reception of community ARV delivery the endogenous independent variable.

The primary endpoint is defined as having a VL $\geq$ 1,000 copies/ml at study exit. The primary endpoint is examined using a log-binomial model because this regression model yields an RR that allows for a more intuitive interpretation than an odds ratio. Whether or not the RR is below the non-inferiority margin is assessed using the upper bound of a one-sided 95 per cent CI (equivalent to the upper bound of a two-sided 90% CI).

If the upper bound of this CI for the RR comparing intervention to control is below 1.45, the intervention is deemed non-inferior to the control. If the upper bound is greater than or equal to 1.45, then the null hypothesis that the intervention is inferior to the control cannot be rejected (at the alpha equal to 0.05 level) and thus the results of the trial are inconclusive. The CI is obtained from the log-binomial model adjusting standard errors for clustering at the level of a healthcare facility.

The primary model regresses viral failure at study exit onto a binary variable for having been randomized to an intervention facility. In secondary analyses, we adjust for having had a suppressed VL at baseline, follow-up time, time between the blood sample for the baseline and the study exit VL, and age and sex.

The secondary endpoint (participants' out-of-pocket healthcare expenditures during the past six months) is analyzed using ordinary least squares regression (for inference based on the mean expenditure) and median regression (for inference based on the median expenditure), with statistical significance being assessed using randomization inference (as implemented in the most recent Stata package (Heß 2017)).

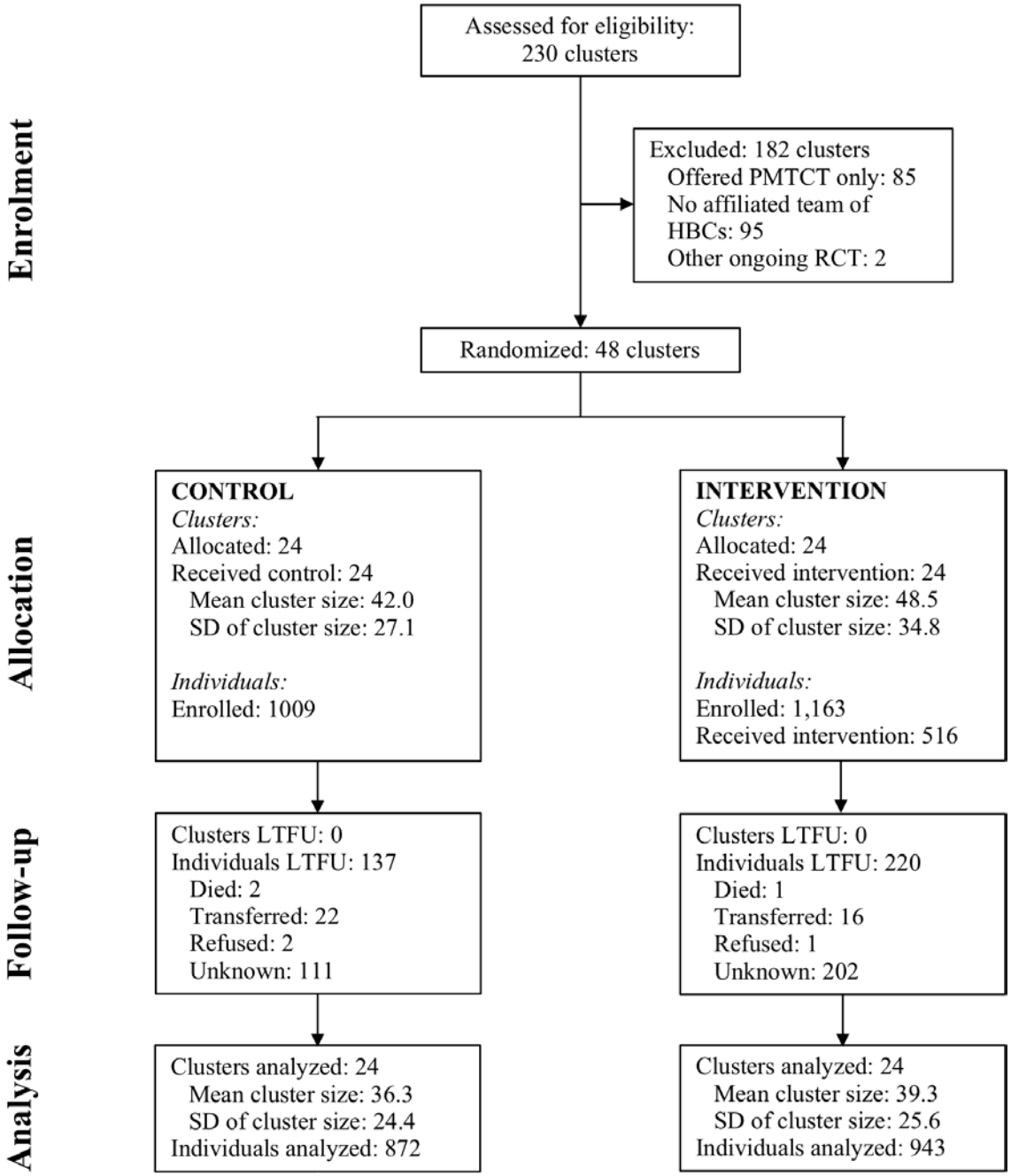
Randomization inference has recently been recommended for the analysis of cluster-randomized trials (especially with varying cluster sizes) by leading econometricians,

(Athey and Imbens 2016) and applied in several papers in high-impact economics and political science journals (Cohen and Dupas 2010; Ichino et al. 2012) by specifying the randomization scheme of the study, the randomization inference routine adjusted for clustering at the level of the healthcare facility, as well as the matched-pair design.

3.9 Sample characteristics

Figure 2 shows the progression of healthcare facilities (clusters) and participants through the trial.

Figure 2: Flowchart showing progression of clusters (healthcare facilities) and participants through the trial



Abbreviations: PMTCT = prevention of mother-to-child transmission of HIV; HBC = home-based carer; RCT = randomized controlled trial; SD = standard deviation; LTFU = lost to follow-up

In total, 48 healthcare facilities and 2,172 participants were enrolled into the trial. There were 24 healthcare facilities with a total of 1,009 participants enrolled in the control arm (standard facility-based care). An additional 24 healthcare facilities with a total of 1,163 participants were enrolled in the intervention arm (standard facility-based care for those unstable on ART and ARV community delivery for those stable on ART).

Of the participants enrolled in the intervention arm, 516 (44.4%) received ARV community delivery. For 63 (12.2%) of these participants, no VL taken after enrolment into the trial is available and they are considered lost to follow-up. For a further 69 (13.4%) of these participants, the only available VL after enrolment was taken prior to receiving the first ARV community delivery visit. These participants are kept in the sample for the primary analysis because they may have indirectly benefited from other participants in their healthcare facility receiving ARV community delivery.

We also show results when restricting ARV community delivery recipients to only those who have received ARV community delivery for at least 90 and 180 days. The mean duration of receiving ARV community delivery (among the 359 participants for whom we have a study exit VL taken after receiving the first ARV community delivery visit) is 226 days, with a standard deviation (SD) of 123 days (median of 213 days with an interquartile range of 138–300 days).

Some participants (35, 6 of whom were lost to follow-up) received ARV community delivery but did not continue until the end of the trial period. Of these, 4 transferred to a healthcare facility outside of Dar es Salaam; 8 informed the study team that they wanted to return to standard facility-based care; 3 were returned to standard facility-based care because they were enrolled based on a CD4-cell count > 350 cells/µl but the VL taken at enrolment came back as being non-suppressed; 1 died; 1 was imprisoned; 3 became pregnant and entered into the prevention of mother-to-child transmission of HIV (PMTCT) program (without ARV community delivery); and the remainder could not be found again by the HBC.

In the control arm, 13.6 per cent (137/1,009) were lost to follow-up (LTFU) and in the intervention arm, 18.9 per cent (220/1,163), yielding a sample size for analysis of 872 participants in the control arm and 943 in the intervention arm.

The sample characteristics for clusters (a healthcare facility with its catchment area) are shown in Table 1. Table 2 displays the sample characteristics of individuals at the time of the baseline assessment.

Table 2: Sample characteristics at baseline among participants not LTFU

	Control	Intervention
n	872	943
Male, n (%)	129 (15.4)	203 (22.2)
Missing, n (%)	33 (3.8)	30 (3.2)
Age, mean (SD)	38.7 (8.6)	40.5 (9.4)
Missing, n (%)	40 (4.6)	35 (3.7)
Age group, *n (%)*		
18–25 years	41 (4.9)	32 (3.5)
26–35 years	260 (31.2)	259 (28.5)
36–45 years	371 (44.6)	384 (42.3)
46–55 years	129 (15.5)	171 (18.8)
56–65 years	25 (3.0)	53 (5.8)
> 65 years	6 (0.7)	9 (1.0)
Education, n (%)		
< Primary school	26 (4.3)	66 (9.8)
Primary school	473 (77.7)	512 (76.1)
Secondary school	110 (18.1)	95 (14.1)
Missing, n (%)	263 (30.2)	270 (28.6)
Married, n (%)	237 (35.8)	334 (44.3)
Missing, n (%)	210 (24.1)	189 (20.0)
Time on ART in days, mean (SD)	1059 (952)	1407 (1171)
Missing, n (%)	277 (31.8)	304 (32.2)
Time on ART, n (%)		
< 90 days	57 (9.6)	48 (7.5)
90–179 days	34 (5.7)	19 (3.0)
180–364 days	73 (12.3)	58 (9.1)
1 to < 3 years	210 (35.3)	202 (31.6)
3 to < 5 years	109 (18.3)	121 (18.9)
≥ 5 years	112 (18.8)	191 (29.9)
Disclosed HIV status to at least one person, n (%)	542 (88.4)	625 (92.0)
Missing, n (%)	259 (29.7)	264 (28.0)
VL ≥ 1,000 copies/ml or CD4 <350 cells/μl, n (%)		
	132 (17.4)	122 (15.4)
Missing, n (%)	114 (13.1)	150 (15.9)

Abbreviations: SD = standard deviation; ml = milliliter; μl = microliter

Participants in the intervention arm were somewhat more likely to be male (22.2% versus 15.4%), married (44.3% versus 35.8%), and to self-report at baseline having been on ART for a longer time (mean of 1,407 versus 1,059 days). The percentage in viral failure or (if a VL measurement was not available) having a CD4-cell count < 350 cells/μl at baseline was similar between the two study arms.

The mean follow-up time was 326 days (SD: 125) in the control and 327 days (SD: 120) in the intervention arm. Median follow-up time was also similar between the study arms: 318 days in the control and 322 days in the intervention arm.

Table 3 shows that the baseline characteristics of those who were LTFU are similar to those who are included in the analysis except that they are (1) less likely to have received the intervention; and (2) more likely to have been in viral failure or had a CD4-cell count < 350 cells/μl at baseline.

Table 3: Sample characteristics comparing those LTFU with those included in the analysis

	Control		**Intervention**	
	Not LTFU	*LTFU*	*Not LTFU*	*LTFU*
n	872	137	943	220
Male, n (%)	129 (15.4)	22 (19.3)	203 (22.2)	21 (15.4)
Age in years, mean (SD)	38.7 (8.6)	38.9 (9.4)	40.5 (9.4)	39.1 (9.9)
Age group, n (%)				
18–25 years	41 (4.9)	6 (5.4)	32 (3.5)	10 (7.6)
26–35 years	260 (31.2)	34 (30.6)	259 (28.5)	39 (29.8)
36–45 years	371 (44.6)	48 (43.2)	384 (42.3)	52 (39.7)
46–55 years	129 (15.5)	16 (14.4)	171 (18.8)	22 (16.8)
56–65 years	25 (3.0)	6 (5.4)	53 (5.8)	7 (5.3)
> 65 years	6 (0.7)	1 (0.9)	9 (1.0)	1 (0.8)
Education, n (%)				
< Primary school	26 (4.3)	3 (4.2)	66 (9.8)	6 (6.2)
Primary school	473 (77.7)	51 (71.8)	512 (76.1)	76 (78.4)
Secondary school	110 (18.1)	17 (23.9)	95 (14.1)	15 (15.5)
Married, n (%)	237 (35.8)	20 (27.4)	334 (44.3)	39 (39.4)
Time on ART in days, mean (SD)	1,059 (952)	1,199 (1,097)	1,407 (1,171)	1,438 (1,183)
Time on ART, n (%)				
< 90 days	57 (9.6)	8 (11.3)	48 (7.5)	7 (7.7)
90–179 days	34 (5.7)	6 (8.5)	19 (3.0)	4 (4.4)
180–364 days	73 (12.3)	3 (4.2)	58 (9.1)	4 (4.4)
1 to < 3 years	210 (35.3)	25 (35.2)	202 (31.6)	33 (36.3)
3 to < 5 years	109 (18.3)	12 (16.9)	121 (18.9)	14 (15.4)
≥ 5 years	112 (18.8)	17 (23.9)	191 (29.9)	29 (31.9)
Disclosed HIV status to at least one person, n (%)	542 (88.4)	67 (93.1)	625 (92.0)	90 (92.8)
VL ≥ 1,000 copies/ml or CD4 < 350 cells/μl, n (%)	132 (17.4)	29 (28.2)	122 (15.4)	23 (19.8)
Received the intervention, n (%)	0 (0.0)	0 (0.0)	453 (48.0)	63 (28.6)

Abbreviations: SD = standard deviation; ml = milliliter; μl = microliter

4. Results

4.1 Exposure to the intervention and HBC performance

Over the course of the study period, a total of 151 HBCs (50 in Temeke, 45 in Kinondoni, and 56 in Ilala) conducted 3,039 household visits to 516 participants for ARV community delivery. Intervention recipients received a mean of 5.9 household visits (and a median of 6.0) for ARV community delivery during the trial period. Over the course of the study, 12 participants contacted the study team to inform them that the HBC had not delivered their ARV supply on time; these 12 participants were under the responsibility of a total of four HBCs.

In the study exit questionnaire, 83.1% (295/355, the denominator being all those who received ARV community delivery and for whom data from the study exit questionnaire was available) reported being "very satisfied" with the ARV community delivery program (Figure 3); 88.7% (315/355) reported that the HBC always delivered the ARVs on time (Figure 4); and 2.0% (7/355) reported that they had to miss a dose of ARVs because the HBC did not deliver ARVs on time.

Figure 3: Histogram of satisfaction with the ARV community delivery among those who received it

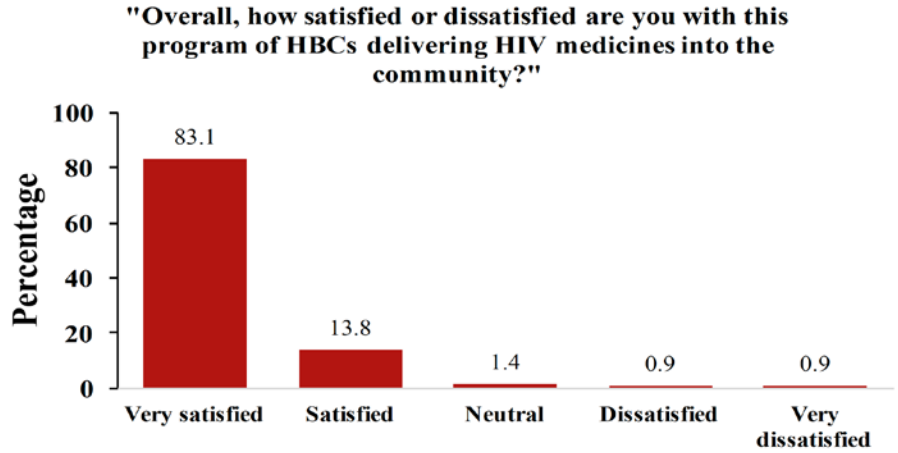
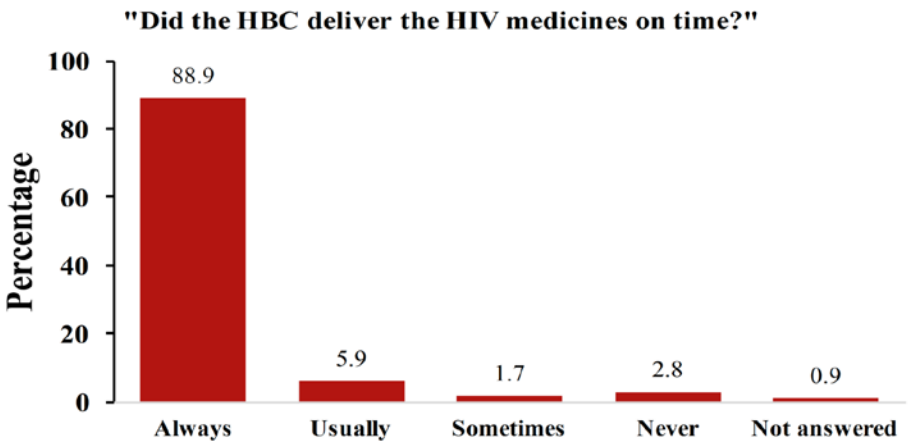


Figure 4: Histogram of participants' responses as to whether the home-based carer delivered ARVs on time



Of those who received ARV community delivery, 96.3% (342/355) reported that they would like to continue with the program (rather than return to standard facility-based care) and 99.7% (354/355) said they would recommend it to other communities. However, 0.9% (3/355) of participants who received ARV community delivery reported that the program led to an unintentional disclosure of their HIV status to a third person.

4.2 Uptake of the intervention

Of participants who were offered ARV community delivery (in other words, who were clinically stable on ART and attended care at a healthcare facility randomized to ARV community delivery), 87.4 per cent decided to enroll in the program rather than remain in standard facility-based ART care. In semi-structured qualitative interviews with eight participants who refused ARV community delivery, we found that confidentiality concerns were often a reason for declining to participate in the intervention. Most individuals worried that their status would be unintentionally disclosed due to the presence of an HBC in the community or within their home:

> It may happen that the person who brings me medicine has friends in the community who they may run into and tell why they are in the neighborhood. So, others may know my status and maybe stigmatize me. — Female, 28 years

In some cases, individuals had yet to disclose their status to their own families; in other cases, individuals had already shared their status with their families, but were concerned that others within the community would find out.

In addition to confidentiality concerns, respondents indicated that picking up their medications at the facility meant that they could also see a physician or nurse, something that would not be possible were the medications delivered to them:

> I know if I come here I can get ART as usual and I will also do a check-up. That's why I prefer to get services here at the facility. — Female, 33 years

Some individuals said that although it may be convenient to receive medications at home, visiting the facility on a frequent basis meant that other illnesses were more likely to be addressed in a timely way by physicians or nurses they already knew and with whom they were satisfied.

It also emerged that interviewees were not concerned about some of the reasons that we hypothesized might drive people to opt against ARV community delivery. Participants generally had faith that if they were enrolled in the program, HBCs would likely deliver medications on time:

> I believe that they [ARVs] would be delivered on time and even if they were not, there would not be a delay of several days. — Male, 39 years

Similarly, with a few exceptions, interviewees were generally not concerned about the possibility of HBCs failing to find their household or that they may not be present at the time of the visit. The few interviewees who indicated that they thought it was possible for them not to be at home at the time of the HBC visit were not concerned about failing to receive their medications. Instead, interviewees were concerned that: (1) it would be an

inconvenience for HBCs to have to return to their household later; and (2) HBCs would search for them in the community thereby risking exposing their status.

4.3 Viral failure

At the end of the study period (defined by the time of measurement of the study exit VL), 10.9 per cent (95/872) and 9.7 per cent (91/943) are in viral failure in the control and intervention arms, respectively. Among those who have a suppressed VL at baseline, 4.3 per cent (27/626) and 4.6 per cent (31/671) are in viral failure at study exit in the control and intervention arms, respectively. Among those who received ARV community delivery, 5.7 per cent (26/453) are in viral failure at study exit. When restricting the sample to those who had received ARV community delivery for at least 90 days prior to the study exit VL measurement, 7.0 per cent (24/345) are in viral failure.

The RR for viral failure comparing intervention to control arm participants is 0.89 (95% CI: 0.63–1.25) in the primary (unadjusted) model (see Table 4).

Table 4: Effect of the intervention on the risk of viral failure[1]

	Unadjusted[2]	**Adjusted for baseline VL/CD4[3]**	**Adjusted for baseline VL/CD4, age and sex[4]**
n	1,815	1,551	1,494
RR (two-sided 95% CI)	0.89 (0.63–1.25)	0.96 (0.71–1.29)	1.00 (0.74–1.35)
p[5]	0.489	0.766	0.998
One-sided 95% CI	1.00–1.18	1.00–1.23	1.00–1.28

[1] In all models, standard errors were adjusted for clustering at the healthcare facility level.
[2] This log-binomial model regressed viral failure (binary) onto intervention arm (binary).
[3] This log-binomial model regressed viral failure (binary) onto intervention arm (binary) and a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline.
[4] This log-binomial model regressed viral failure (binary) onto intervention arm (binary), a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl), age (continuous), and sex (binary).
[5] The p-value tests the null hypothesis that the RR equals 1.0 with a significance level of alpha ≤ 0.05.

The upper bound of the one-sided 95 per cent CI for this RR is 1.18 (and therefore below the non-inferiority margin of 1.45). When the sample is restricted to those participants with a suppressed VL (< 1,000 copies/ml) at baseline—57.6% (440/764) of whom received ARV community delivery (as opposed 48.0% when including all ART patients at intervention facilities)—the RR is above one and the upper bound of the one-sided 95 per cent CI above the non-inferiority margin in all models (Appendix Table A3).

In the Appendix, we also show results when: (1) adjusting for follow-up time and time between the baseline and endline VL measurement (Appendix Table A2); (2) when restricting the sample to those for whom the study exit VL was taken at least 200 days after enrolment into the trial (Appendix Table A4); and (3) when restricting the sample to those for whom the study exit VL was taken at least 200 days after the baseline VL (or CD4-cell count) (Appendix Table A5).

The complier average causal effect (in other words, the effect of ARV community delivery on those who received ARV community delivery) is not significantly different from zero in all models (see Table 5).

Table 5: Estimates of the complier average causal effect using instrumental variable regression[1]

	Unadjusted[2]	Adjusted for baseline VL/CD4[3]	Adjusted for baseline VL/CD4, age, and sex[4]
n	1,815	1,551	1,494
Coefficient (95% CI)	-0.026 (-0.099–0.047)	-0.006 (-0.063–0.052)	0.002 (-0.055–0.058)
p[5]	0.487	0.848	0.951

[1] All models are ordinary least squares regression models, with the endogenous independent variable being a binary indicator for whether the participant received ARV community delivery and the instrument being a binary indicator for study arm. Standard errors were adjusted for clustering at the healthcare facility level.
[2] This model included intervention arm (binary) only as independent variable.
[3] This model included intervention arm (binary), and a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/μl) at baseline as independent variables.
[4] This model included intervention arm (binary), a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/μl) at baseline, age (continuous), and sex (binary) as independent variables.
[5] The p-value tests the null hypothesis that the coefficient equals 0.0 with a significance level of alpha $\leq$ 0.05.

The regression coefficients in Table 5 can be interpreted as the absolute difference in the probability (between zero and one) of viral failure in the intervention arm compared to the control. In the unadjusted model, receiving the intervention leads to a 2.6 percentage point lower probability of being in viral failure at the end of the study period compared to being in the control. In the Appendix, we show the complier average causal effect under different model specifications and sample restrictions (Appendix Table A6), and when restricting the sample to those who have a suppressed VL at baseline.

4.4 Participants' healthcare expenditures

4.4.1 Cost to the patient of an ART care visit

In the study exit questionnaire, participants reported having incurred a median cost of TZS 800 (PPP$ 1.16) with an interquartile range of TZS 0–2,000 (PPP$ 0.00–2.89). The mean cost was TZS 3,445 (PPP$ 4.98) with a standard deviation of TZS 16,795 (PPP$ 24.29). These costs include money lost from income-generating activities due to the time taken to attend care. The costs for the ART care visit on the day of the baseline questionnaire were broadly similar with a median of TZS 800 (interquartile range (IQR): TZS 0–3,000) and mean of TZS 5,831 (SD: TZS 24,863), equal to PPP$ 1.16 (IQR PPP$ 0–4.34) and PPP$ 8.43 (SD: PPP$ 35.96), respectively.

The median and mean for an ART care visit do not differ significantly when restricting the sample to those who are clinically stable on ART or those who have received ARV community delivery. Among those enrolled in the ARV community delivery program, 55 per cent are scheduled to pick up their ARVs from the facility once per month and 45 per

cent every two months. Thus, by enrolling in ARV community delivery (which only requires a visit once per year to the healthcare facility for a clinical check-up), these participants have on average 8.3 visits fewer per year for ART care. Using our figure for the cost of an ART care visit in Dar es Salaam, simple extrapolation suggests that receiving ARV community delivery with an annual check-up at the healthcare facility will reduce a patient's cost to attend ART care by a median of TZS 6,640 (PPP$ 9.61) per year.

4.4.2 Healthcare expenditures during the past six months

In the study exit questionnaire, only 36.6 per cent of participants at intervention facilities and 6.5 per cent at control facilities reported having attended a public primary care or private doctor during the past six months, suggesting that most participants may have misunderstood the healthcare expenditure questions as excluding ART care visits. Table 6 shows that there is no statistically significant difference in the mean or median healthcare expenditures of patients between the control and intervention arms.

Table 6: Impact of the intervention on participants' healthcare expenditures during the preceding six months

Inference based on the mean (TZS)				Inference based on the median (TZS)			
Control (95% CI)	*Intervention (95% CI)*	*Coefficient (95% CI)[1]*	*P[2]*	*Control (IQR)*	*Intervention (IQR)*	*Coefficient (95% CI)[3]*	*P[2]*
2,312 (1,863–2762)	4,483 (2,890–6,077)	1,529 (138–2,920)	0.092	800 (800–2,000)	800 (0–3,000)	-400 (-2,368–568)	0.076

Abbreviation: IQR = interquartile range

[1] As obtained from an ordinary least squares regression of cost onto an indicator for intervention or control facility and indicator variables for each facility pair (as used in the matched-pair randomization). Standard errors were adjusted for clustering at facility level.

[2] As obtained from randomization inference with 10,000 repetitions.

[3] As obtained from a median regression of cost onto an indicator for intervention or control facility and indicator variables for each facility pair (as used in the matched-pair randomization). Standard errors were adjusted for clustering at facility level.

4.5 Percentage of ART patients shifted to community-based care

The percentage of all ART patients at each intervention facility who are enrolled in ARV community delivery varies from 0.3% to 19.0%, with an unweighted mean of 4.4% (see Table 7).

Table 7: Percentage of ART patients at each intervention facility that enrolled in ARV community delivery

Facility name	ART patients	No. in intervention	% of ART patients 'shifted' into the community
Arafa Ugweno	202	6	3.0
Buza	215	18	8.4
Goba	177	17	9.6
Hananasif	530	18	3.4
Keko	79	15	19.0
Kigogo	347	10	2.9
Kimbiji	119	15	12.6
Kinyerezi	238	6	2.5
Kitunda	768	16	2.1
Mabibo	278	12	4.3
Mbagala Rangi Tatu	15,663	75	0.5
Mbezi	870	3	0.3
Mburahati	1,639	76	4.6
Mji mwema	161	11	6.8
Mongolandege	152	5	3.3
Mwenge	1,597	47	2.9
Pugu Kajiungeni	561	16	2.9
Tabata	2,193	33	1.5
Tabata NBC	249	6	2.4
Tambukareli	1,554	24	1.5
Tandale	2,951	20	0.7
Toa Ngoma	239	12	5.0
Vingunguti	1,865	42	2.3
Yombo Makangarawe	544	20	3.7

4.6 Costs of the intervention

The total cost of the intervention was TZS 197,900,500 (PPP$ 286,227) (see Table 8).

Table 8: Start-up and running costs of the intervention

Cost item	TZS	PPP$
Start-up costs		
Creation of the training package for HBCs and HBC supervisors	4,085,000	5,908
Training of HBCs and HBC supervisors	37,188,000	53,786
Meetings with the healthcare facility heads	6,477,500	9,369
Allowances for the National AIDS Control Program	2,700,000	3,905
Total start-up costs	*50,450,500*	*72,968*
Running costs		
HBC stipends[1] – Temeke	74,635,000	107,948
HBC stipends[1] – Kinondoni	43,860,000	63,437
HBC stipends[1] – Ilala	22,130,000	32,008
Regular meetings with HBC supervisors	4,500,000	6,508
Total running costs	*145,125,000*	*209,901*
Total	**195,575,500**	**282,869**

[1]These payments to HBCs were in addition to the regular payments HBCs received (independently of this study).

Over the course of the study period, a total of 151 HBCs (50 in Temeke, 45 in Kinondoni, and 56 in Ilala) conducted 3,039 household visits to 516 participants for ARV community delivery. Intervention recipients received a mean of 5.9 household visits (and median of 6.0) for ARV community delivery during the trial period.

Given that 521 participants received ARV community delivery, the cost per intervention recipient was TZS 379,847 (PPP$ 549). A total of 151 HBCs conducted 3,039 ARV community delivery visits. Thus, the total cost per ARV community delivery visit was TZS 65,120 (PPP$ 94) and TZS 47,754 (PPP$ 69) when including and excluding start-up costs, respectively. These cost figures do not include the salary of the data collection officers, who were stationed at each of the healthcare facilities and were primarily responsible for questionnaire administration. The majority (72%) of the expenses were for the HBC stipends. Apart from the TZS 50,000 per month that HBCs received from the government, the study paid HBCs at intervention facilities an additional TZS 75,000 flat payment per month, which was changed to a payment of TZS 10,000 per community ARV delivery visit in January 2017.

4.7 Qualitative findings

4.7.1 Implementation of ARV community delivery by HBCs

Semi-structured qualitative interviews with HBCs provided insight into how they implemented ARV community delivery. HBCs keep a record of their clients, which includes information on previous and upcoming visits to the clinic, date of prescription pick-ups, anthropometry measurements and type of advice or education session given at each HBC visit. For ARV community delivery clients, HBCs typically pick up the prescription from the healthcare facility 2–3 days before the client would be due to attend the healthcare facility for their ARV refill.

HBCs then coordinate with their clients and arrange a place to meet, usually at the participants' residences or in public areas such as business centers and bus stations. When HBCs meet participants, they provide the antiretroviral pills, record the participants' signature, take a weight measurement, provide advice and ask participants about their overall health since the previous visit. HBCs mentioned instances where they had advised participants to seek further attention at the clinic for abnormal side-effects or co-morbidities.

4.7.2 Concerns about stigma

Some of the HBCs noted that participants' concerns about unintentional disclosure of their HIV status (and fear of resulting stigma) inhibits some people living with HIV to seek healthcare at the clinic. Specifically, HBCs felt that some clients are afraid that people might recognize them at the clinic and thus delay attending, resulting in poor adherence to ART. Several HBCs argued that there is more privacy when the healthcare worker comes to your house to deliver ARVs. HBCs also reported taking additional precautions to avoid unintentional disclosure of HIV status, such as by not wearing uniforms or not carrying bags or personal items that openly display the MDH logo:

> Initially when people were introduced to this program they were worried that we will deliver medicine openly like vegetables. — Male, 41 years, HBC

> I told her there is a home delivery service and she said, "Ah, I don't want cars." I told her there're no cars—I come wearing normal clothes like your daughter. Would that be a problem? She said, "If that is the case I will come next week for registration." Some people think it would be like before—using MDH cars to track people or wearing uniforms. — Female, 43 years, HBC

4.7.3 HBCs' and participants' satisfaction with the ARV community delivery program

HBCs and participants were overwhelmingly positive about the ARV community delivery program. One of the most common reasons HBCs cited was the efficiency of the service, which allows participants to continue their income-generating activity for the day. HBCs felt that because many of the participants are self-employed in food vending, tailoring and other small business activities, missing a day of work to travel to the clinic can have adverse effects on food security for the household (as daily wages are instrumental for food purchases for the day).

Similarly, many participants mentioned that there was a large cost to attend facility-based care in terms of bus fare, wait time and food purchase at the clinic due to long wait times. Congestion at the clinic was a repeated concern from both the HBCs and participants. One participant said:

> You may wake up in the morning and do business and earn money. But then when you go to Kitunda [clinic] it takes until 12 or 1pm before you get your service. Ever since they started this service of home delivery it has been so nice and very helpful. It doesn't require a lot of time as it would at Kitunda. — Male, 43 years, study participant

4.7.4 Social support for participants and community standing of HBCs

In addition to the economic benefits of ARV community delivery, participants reported that HBCs' home visits were personal and provided social support. Participants felt that the HBCs care for their wellbeing while providing an opportunity to socialize. These emotional sentiments were also present in the interviews with the HBCs. HBCs mentioned that they have an opportunity to get to know participants and understand their social environment:

> For instance, when you deliver medicine, you may find the [clients'] weight has increased…but you also get a chance to talk to the client for a long time, so you get to know his/her health and living status. You may recognize clients' risk behaviors like drunkenness when you pay a home visit [so] you may recognize the living environment and manage to correct him/her. — Male, 36 years, HBC

HBCs also reported feeling valued and respected since the start of the ARV community delivery program. Because of the time efficiency of the service to the participants, HBCs felt they were appreciated and thus managed to build close relationships with their clients. Some mentioned receiving small gifts of appreciation, which often included prepared food or vegetables from participants' gardens.

4.7.5 Need for further training

Many HBCs felt that they should receive additional training to be in a better position to answer their clients' questions. Such questions included:

> What is the difference between the person who is using ARVs and the one who use Septrin [co-trimoxazole]. The client is using ARVs and the wife is using Septrin. — Female, 42 years, HBC
>
> I want to conceive and you ask me to use condoms. How does that work? — Female, 47 years, participant

Other questions concerned the dosage of medicines, (reasonable) alcohol consumption and co-morbidities.

5. Discussion

5.1 Summary of findings

The RR for viral failure comparing intervention to control participants is 0.89 with the upper bound of the one-sided 95% CI being 1.18 and thus below the non-inferiority margin. It therefore appears that ARV community delivery is unlikely to have substantially adverse effects on the health of participants. However, while participants' satisfaction with the program is high and ARV community delivery will likely save patients substantial amounts of time, two envisaged benefits of the program—decongestion of healthcare facilities and reductions in patients' healthcare expenditures—are minimal.

The intervention shifted only a mean of 4.4 per cent of ART patients from facility- to community-based care, which is unlikely to have had a noticeable effect on clinicians' workloads and waiting times at healthcare facilities (especially since ART patient volumes are generally rising in SSA) (Wang et al. 2016). Regarding patients' ART care expenditures, the median cost of attending one ART care visit for participants is only TZS 800 (PPP$ 1.16). Thus, for a participant scheduled to attend ART care every two months, enrolling in ARV community delivery with an annual check-up at the healthcare facility will only reduce the participant's expenses for ART care by a median of TZS 4,000 (PPP$ 5.79) per year.

5.2 Key considerations for local policymakers

Table 9 summarizes the key advantages and disadvantages of the ARV community delivery program.

Table 9: Key considerations for local policymakers regarding ARV community delivery

Positive	Neutral	Negative
• High patient satisfaction with the program • Slight reduction in patients' ART care expenses • Small reduction in ART patient volume at healthcare facilities • Likely time-saving for patients • Possibly higher long-term retention in ART care	• Likely no substantial adverse effects on patients' health	• Costs of running the program • Risk of some patients not attending their yearly clinical check-up • May require the support of an additional staff member for successful implementation

The running costs of the program consist virtually entirely of the HBC stipends. Regarding retention in care: it appears that ARV community delivery may improve long-term retention in care. Only six participants (0.12% of those receiving ARV community delivery) were lost in the intervention for reasons other than returning to standard facility-based care (many because their baseline VL made them ineligible for ARV community delivery), entering PMTCT care, being transferred to a healthcare facility outside of Dar es Salaam or imprisonment.

However, as participants in the ARV community delivery program continued to receive ARVs from the HBC regardless of whether they attended their annual check-up at the healthcare facility, there may be a low motivation among intervention recipients to attend an annual check-up. This in turn may mean long periods of time without contact with a nurse or physician.

Lastly, it should be noted that, despite HBCs and their supervisors being responsible for implementation of the program, the (intermittent) presence of a data collection officer at the healthcare facility may well have led to a better implementation of the program than would have been the case had the data collection officers not been present (as might be the case in a routine rollout).

5.3 Increasing enrolment in ARV community delivery

An important limitation of the ARV community delivery program, as implemented in this study, is that it allowed for only a small proportion of ART patients at the study's healthcare facilities to be enrolled in the program. Table 10 outlines possible ways of increasing enrolment in ARV community delivery.

Table 10: Possibilities to increase enrolment in ARV community delivery

Possible modification	Advantages	Disadvantages
1. Remove eligibility criterion that a patient must reside in the facility's catchment area	Likely to lead to a large increase in enrolment	Logistically complex and possibly costly to implement
2. Increase number of ART care facilities in Dar es Salaam that have an affiliated team of HBCs	Would increase the number of healthcare facilities offering ARV community delivery	Cost of training and employing additional HBCs
3. Offer enrolment to all ART patients if they can meet with the HBC within the facility's catchment area	Likely to lead to a large increase in enrolment	Would not reduce transport time and costs (only time lost from waiting at the healthcare facility)
4. Removing or relaxing eligibility criterion that participants must be clinically stable on ART at enrolment	Would only lead to a small increase in enrolment	May be deemed unsafe
5. Do not use HBCs to deliver ARVs into the community (for example, delivery personnel on motorcycles)	Depending on the details of the scheme, may lead to a large increase in enrolment	May be costly, would not build on a possible rapport between HBCs and their clients; the non-HBC cadre may not recognize symptoms/signs that require referral to a healthcare facility

The main reason for low enrolment is the eligibility criterion that a patient must reside in the facility's catchment area. This is mainly because many ART patients in Dar es Salaam do not attend the healthcare facility closest to where they live. Removing this eligibility restriction would greatly increase the proportion of ART patients eligible for ARV community delivery at a healthcare facility. However, an important drawback is that ARV community delivery would become logistically more complex (and possibly costlier to implement): either HBCs would have to travel across the entire city to deliver ARVs, or an HBC affiliated with a different healthcare facility than the patient is attending (in the catchment area where the patient resides), would be tasked with ARV community delivery for the patient.

The former (HBCs traveling across the entire city to deliver ARVs to patients) would be costly to implement due to the much higher transport costs compared to the current scheme. The latter would be unlikely to add substantial costs to the program trialed in this study, but would be logistically more complex to implement because it would require communication across healthcare facilities.

At the time of study conception, the study team felt that establishing such a mechanism would be logistically too complex to be successful. However, given the low proportion of ART care patients who can be reached with the ARV community delivery program in its current form, future research should explore the logistical feasibility and cost of a more ambitious program such as this.

A second possibility to increase the number of patients enrolled in the HBC-led ARV community delivery program is to expand the number of healthcare facilities in Dar es Salaam that have an affiliated team of HBCs. At the time of study conception, only 37% (53/145) of healthcare facilities that offered ART care in Dar es Salaam also had a team of HBCs.

A third possibility is to offer enrolment in the ARV community delivery program to all ART patients if they can meet with the HBC within the facility's catchment area. This would allow those who do not reside in the facility's catchment area to still benefit from ARV community delivery by foregoing the time spent waiting at the healthcare facility to pick up a new supply of ARVs.

A fourth possibility, removing or relaxing the eligibility criterion that participants must be clinically stable on ART at enrolment into ARV community delivery, would only lead to a small increase in enrolment. In this study, removing the clinical stability criterion for eligibility would have led to an increase in enrolment of only 15.7 per cent.

Lastly, one can imagine a scheme that delivers ARVs to patients' homes (or other meeting points in the community) but does not use HBCs. However, this would have the disadvantage that the program does not build on any existing rapport that HBCs may have built over time with their clients. In addition, the non-HBC cadre may be unable to recognize any symptoms or signs that require referral to a nurse or physician.

5.4 Limitations

This study had several limitations. Firstly, only a relatively small proportion of ART patients at intervention facilities were enrolled in the ARV community delivery program: 48.0 per cent (453/943) of participants at intervention facilities were enrolled in ARV community delivery and 41.3 per cent (345/835) received ARV community delivery for at least 90 days before the study exit VL measurement was taken.

The primary analysis in our study protocol, however, included all ART patients at a healthcare facility who resided in the facility's catchment area because patients at intervention facilities who remain in facility-based care may indirectly benefit from ARV community delivery through the envisaged decongestion of a healthcare facility. All else being equal, the lower the proportion of ART patients enrolled in ARV community delivery at an intervention facility, the more likely the intervention is to have a null effect.

Therefore, if the intervention was somewhat inferior to the control, this study may have found the intervention to be non-inferior based on this 'dilution' of the intervention effect. To try to ascertain whether the non-inferiority stems mostly from this dilution effect, we show the results when restricting the sample to only those who had a suppressed VL at baseline—58.9 per cent (395/671) of whom received ARV community delivery—in secondary analyses.

The RR in the unadjusted model among this sample is 1.07, but the upper bound of the one-sided 95 per cent CI (1.75) is above the non-inferiority margin (1.45), largely because this study is not powered to determine non-inferiority among this smaller sample of participants. We also calculate the complier average causal effect (in other words, the effect of the ARV community delivery program on its recipients) and find that the point estimates are generally close to zero (although the CIs are fairly wide).

Secondly, the proportion of LTFU—13.6 per cent (137/1,009) in the control arm and 18.9 per cent (220/1,163) in the intervention arm—is relatively high. While the characteristics of those LTFU is similar to those included in the analysis, we cannot exclude the possibility that those who were LTFU in the intervention arm had different outcomes compared to those LTFU in the control arm. It is also possible that some of those who were LTFU in the control arm switched to a healthcare facility that provided ARV community delivery because they heard about the program. Unfortunately, our data do not allow us to assess to what degree such a switching from control to healthcare facilities may have occurred during the study period.

Thirdly, participants in the control arm appear to not have included ART care visits when answering questions on health service utilization in the preceding six months. However, given the low costs incurred from attending ART care, it is unlikely that our estimates of participants' healthcare expenditures during the preceding six months would have been substantially different had participants included ART care in their response. Lastly, with participants receiving ARV community delivery for an average of 226 days, we are unable to assess the longer-term safety of ARV community delivery in this study.

5.5 Conclusions

The ARV community delivery scheme implemented in this trial appears to be non-inferior in terms of viral failure compared to standard facility-based care. In addition, this new healthcare delivery model for ART care experienced high uptake, participants were satisfied with the scheme and it will likely save patients considerable time for ART care.

However, ARV community delivery did not lead to a substantial decrease in participants' healthcare expenditures and the proportion of ART care patients, at an intervention healthcare facility, who were enrolled in the program was small. Local policymakers may consider alterations to this ARV community delivery model to allow a larger proportion of ART patients at healthcare facilities to enroll. Accompanying implementation research would be desirable to establish the effects of such a scheme on patient health and economic outcomes, as well as the health system.

Appendix

Table A1: Activities over the study period

http://www.3ieimpact.org/sites/default/files/2019-01/ie82-chw-delivery-arvs-tanzania-appendix-tablea1.pdf

Table A2: Risk of viral failure, adjusting for follow-up time and time between baseline and endline VL

	n	RR (95% CI)[1]	p[2]	One-sided (95% CI)
Model 1[3]	1,475	1.01 (0.73–1.39)	0.964	1.00–1.32
Model 2[4]	1,266	1.05 (0.75–1.47)	0.791	1.00–1.39
Model 3[5]	1,266	1.02 (0.72–1.44)	0.912	1.00–1.37

Abbreviations: RR = relative risk; CI = confidence interval

[1] In all models, standard errors were adjusted for clustering at the healthcare facility level.

[2] The p-value tests the null hypothesis that the RR equals 1.0 with a significance level of alpha ≤ 0.05.

[3] This log-binomial model regressed viral failure (binary) onto intervention arm (binary), a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline; and the time in days between the enrolment into the trial and the study exit VL measurement (continuous).

[4] This log-binomial model regressed viral failure (binary) onto intervention arm (binary), a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline; and the time in days between the baseline VL (or CD4-cell count) and the study exit VL measurement (continuous).

[5] This log-binomial model regressed viral failure (binary) onto intervention arm (binary), a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline; the time in days between the enrolment into the trial and the study exit VL measurement (continuous); and the time in days between the baseline VL (or CD4-cell count) and the study exit VL measurement (continuous).

Table A3: Risk of viral failure among those who were clinically stable at baseline

	n	RR (95% CI)[1]	p[2]	One-sided (95% CI)
Model 1[3]	1,297	1.07 (0.60–1.92)	0.818	1.00–1.75
Model 2[4]	1,240	1.17 (0.63–2.18)	0.624	1.00–1.97
Model 3[5]	1,051	1.21 (0.64–2.28)	0.555	1.00–2.06
Model 4[6]	1,051	1.22 (0.64–2.34)	0.544	1.00–2.11
Model 5[7]	1,011	1.30 (0.67–2.51)	0.442	1.00–2.25

Abbreviations: RR = relative risk; CI = confidence interval

Note: Clinical stability was defined as having a suppressed VL (< 1,000 copies/ml) at baseline or, if no VL was available at baseline, a CD4-cell count > 350 cells/µl.

[1] In all models, standard errors were adjusted for clustering at the healthcare facility level.

[2] The p-value tests the null hypothesis that the RR equals 1.0 with a significance level of alpha ≤ 0.05.

[3] This log-binomial model regressed viral failure (binary) onto intervention arm (binary).

[4] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); and the time in days between the enrolment into the trial and the study exit VL measurement (continuous).

[5] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); and the time in days between the baseline VL (or CD4-cell count) and the study exit VL measurement (continuous).

[6] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); the time in days between the enrolment into the trial and the study exit VL measurement (continuous); and the time in days between the baseline VL (or CD4-cell count) and the study exit VL measurement (continuous).
[7] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); the time in days between the enrolment into the trial and the study exit VL measurement (continuous); the time in days between the baseline VL (or CD4-cell count) and the study exit VL measurement (continuous); age (continuous); and sex (binary).

Table A4: Risk of viral failure among those for whom the study exit VL was taken at least 200 days after enrolment into the trial

	n	RR (95% CI)[1]	p[2]	One-sided (95% CI)
Model 1[3]	1,567	0.89 (0.61–1.28)	0.526	1.00–1.21
Model 2[4]	1,344	0.95 (0.69–1.31)	0.766	1.00–1.24
Model 3[5]	1,268	1.00 (0.69–1.43)	0.983	1.00–1.35
Model 4[6]	1,097	1.04 (0.74–1.48)	0.810	1.00–1.40
Model 5[7]	1,097	1.01 (0.70–1.46)	0.959	1.00–1.38
Model 6[8]	1,048	1.14 (0.83–1.57)	0.418	1.00–1.49

Abbreviations: RR = relative risk; CI = confidence interval
[1] In all models, standard errors were adjusted for clustering at the healthcare facility level.
[2] The p-value tests the null hypothesis that the RR equals 1.0 with a significance level of alpha ≤ 0.05.
[3] This log-binomial model regressed viral failure (binary) onto intervention arm (binary).
[4] This log-binomial model regressed viral failure (binary) onto intervention arm (binary) and a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline.
[5] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline; and the time in days between the enrolment into the trial and the study exit VL measurement (continuous).
[6] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline; and the time in days between the baseline VL (or CD4-cell count) and the study exit VL measurement (continuous).
[7] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline; the time in days between the enrolment into the trial and the study exit VL measurement (continuous); and the time in days between the baseline VL (or CD4-cell count) and the study exit VL measurement (continuous).
[8] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline; the time in days between the enrolment into the trial and the study exit VL measurement (continuous); the time in days between the baseline VL (or CD4-cell count) and the study exit VL measurement (continuous); age (continuous); and sex (binary).

Table A5: Risk of viral failure among those for whom the study exit VL was taken at least 200 days after the baseline VL (or CD4-cell count)

	n	RR (95% CI)[1]	p[2]	One-sided (95% CI)
Model 1[3]	1,711	0.86 (0.60–1.23)	0.413	1.00–1.16
Model 2[4]	1,447	0.93 (0.68–1.26)	0.633	1.00–1.20
Model 3[5]	1,371	0.98 (0.69–1.37)	0.890	1.00–1.30
Model 4[6]	1,162	1.02 (0.72–1.45)	0.915	1.00–1.37
Model 5[7]	1,162	0.99 (0.68–1.43)	0.950	1.00–1.35
Model 6[8]	1,115	1.11 (0.78–1.57)	0.565	1.00–1.48

Abbreviations: RR = relative risk; CI = confidence interval

[1] In all models, standard errors were adjusted for clustering at the healthcare facility level.

[2] The p-value tests the null hypothesis that the RR equals 1.0 with a significance level of alpha ≤ 0.05.

[3] This log-binomial model regressed viral failure (binary) onto intervention arm (binary).

[4] This log-binomial model regressed viral failure (binary) onto intervention arm (binary) and a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline.

[5] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline; and the time in days between the enrolment into the trial and the study exit VL measurement (continuous).

[6] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline; and the time in days between the baseline VL (or CD4-cell count) and the study exit VL measurement (continuous).

[7] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline; the time in days between the enrolment into the trial and the study exit VL measurement (continuous); and the time in days between the baseline VL (or CD4-cell count) and the study exit VL measurement (continuous).

[8] This log-binomial model regressed viral failure (binary) onto intervention arm (binary); a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline; the time in days between the enrolment into the trial and the study exit VL measurement (continuous); the time in days between the baseline VL (or CD4-cell count) and the study exit VL measurement (continuous); age (continuous); and sex (binary).

Table A6: Robustness checks of the complier average causal effect[1]

	Unadjusted[2]	Adjusted for baseline VL/CD4[3]	Adjusted for baseline VL/CD4, age and sex[4]
Must have ≥90 days between enrolment into ARV community delivery and the study exit VL measurement to be considered to have received the intervention			
n	1,815	1,551	1,494
Coefficient (95% CI)	-0.037 (-0.142–0.067)	-0.008 (-0.090–0.074)	0.003 (-0.078–0.083)
p[5]	0.484	0.847	0.951
Must have ≥180 days between enrolment into ARV community delivery and the study exit VL measurement to be considered to have received the intervention			
n	1,815	1,551	1,494
Coefficient (95% CI)	-0.052 (-0.197–0.093)	-0.011 (-0.125–0.102)	0.004 (-0.108–0.115)
p[5]	0.482	0.847	0.951
Only includes those for whom the study exit VL was taken at least 200 days after the baseline VL (or CD4-cell count) AND must have ≥90 days between enrolment into ARV community delivery and the study exit VL measurement to be considered to have received the intervention			
n	1,711	1,447	1,397
Coefficient (95% CI)	-0.043 (-0.145–0.058)	-0.014 (-0.092–0.065)	-0.003 (-0.080–0.074)
p[5]	0.403	0.736	0.934
Only includes those for whom the study exit VL was taken at least 200 days after the baseline VL (or CD4-cell count) AND must have ≥180 days between enrolment into ARV community delivery and the study exit VL measurement to be considered to have received the intervention			
n	1,711	1,447	1,397
Coefficient (95% CI)	-0.060 (-0.199–0.079)	-0.019 (-0.127–0.089)	-0.004 (-0.110–0.101)
p[5]	0.401	0.735	0.934

Abbreviations: VL = viral load; CD4 = cluster of differentiation 4 cell count; ARV = antiretroviral drugs; CI = confidence interval

[1] All models are ordinary least squares regression models with the endogenous independent variable being a binary indicator for whether the participant received ARV community delivery and the instrument being a binary indicator for study arm. Standard errors were adjusted for clustering at the healthcare facility level.

[2] This model included intervention arm (binary) only as independent variable.

[3] This model included intervention arm (binary) and a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline as independent variables.

[4] This model included intervention arm (binary), a binary indicator for whether the participant was in viral failure (or, if no VL was available, had a CD4-cell count < 350 cells/µl) at baseline, age (continuous) and sex (binary) as independent variables.

[5] The p-value tests the null hypothesis that the coefficient equals 0.0 with a significance level of alpha ≤ 0.05.

Table A7: Complier average causal effect among those who had a suppressed VL at baseline[1]

	Unadjusted[2]	Adjusted for age and sex[3]
n	1,297	1,255
Coefficient (95% CI)	0.005 (-0.038–0.049)	0.009 (-0.036–0.053)
p[4]	0.815	0.708
Must have ≥90 days between enrolment into ARV community delivery and the study exit VL measurement to be considered to have received the intervention		
n	1,297	1,255
Coefficient (95% CI)	0.007 (-0.055–0.070)	0.012 (-0.051–0.076)
p[4]	0.815	0.709
Must have ≥180 days between enrolment into ARV community delivery and the study exit VL measurement to be considered to have received the intervention		
n	1,297	1,255
Coefficient (95% CI)	0.0104 (-0.077–0.098)	0.017 (-0.072–0.106)
p[4]	0.815	0.709
Only includes those for whom the study exit VL was taken at least 200 days after the baseline VL (or CD4-cell count) AND must have ≥90 days between enrolment into ARV community delivery and the study exit VL measurement to be considered to have received the intervention		
n	1,219	1,182
Coefficient (95% CI)	0.008 (-0.056–0.072)	0.014 (-0.051–0.079)
p[4]	0.811	0.676
Only includes those for whom the study exit VL was taken at least 200 days after the baseline VL (or CD4-cell count) AND must have ≥180 days between enrolment into ARV community delivery and the study exit VL measurement to be considered to have received the intervention		
n	1,219	1,182
Coefficient (95% CI)	0.011 (-0.078–0.010)	0.019 (-0.071–0.109)
p[4]	0.811	0.676

Abbreviations: CD4 = cluster of differentiation 4 cell count; CI = confidence interval

[1] All models are ordinary least squares regression models with the endogenous independent variable being a binary indicator for whether the participant received ARV community delivery and the instrument being a binary indicator for study arm. Standard errors were adjusted for clustering at the healthcare facility level.

[2] This model included intervention arm (binary) only as independent variable.

[3] This model included intervention arm (binary), age (continuous) and sex (binary) as independent variables.

[4] The p-value tests the null hypothesis that the coefficient equals 0.0 with a significance level of alpha ≤ 0.05.

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