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RESEARCH ARTICLE

Stability in care and risk of loss to follow-up among clients receiving community health worker-led differentiated HIV care: Results from a prospective cohort study in northern Tanzania

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Abstract

Background: HIV services in Tanzania are facility-based but facilities are often overcrowded. Differentiated care models (DCM) have been introduced into the National Guidelines. We piloted a Community Health Worker (CHW)-led HIV treatment club model (CHW-DCM) in an urban region, and assessed its effectiveness in comparison to the standard of care (SoC, facility-based model), in terms of stability in care, loss to follow-up (LTFU) and treatment adherence.

Methods: In two clinics in the Shinyanga region, clients established on ART (defined as stable clients by national guidelines as on first-line ART >6 months, undetectable viral load, no opportunistic infections or pregnancy, and good adherence) were offered CHW-DCM. This prospective cohort study included all stable clients who enrolled in CHW-DCM between July 2018 and March 2020 (CHW-DCM) and compared them to stable clients who remained in SoC during that period. Multivariable Cox regression models were used to analyse factors associated with continued stability in care and the risk of LTFU during 18 months of follow-up; treatment adherence was assessed by pill count and compared using Chi-square tests.

Results: Of 2472 stable clients, 24.5% received CHW-DCM and 75.5% SoC. CHW-DCM clients were slightly older (mean 42.8 vs. 37.9 years) and more likely to be female (36.2% vs. 32.2%). Treatment adherence was better among CHW-DCM than SoC: 96.6% versus 91.9% and 98.5% versus 92.2%, respectively (both $p = 0.001$). SoC clients were more likely to not remain stable over time than CHW-DCM (adjusted Hazard ratio [AHR] = 2.68; 95% CI: 1.86–3.90). There was no difference in LTFU (adjusted hazard ratio [AHR] = 1.54; 95%CI: 0.82–2.93).

Conclusion: Clients attending CHW-DCM demonstrated better stability in care and treatment adherence than SoC, and the risk of LTFU was not increased. These findings demonstrate the potential of CHW in delivering community-based HIV services in the local Tanzanian context. These results could be used to extend this CHW-DCM model to similar settings.

KEYWORDS
ART, community health worker, differentiated care delivery model, HIV, lost to follow-up, Tanzania, task shifting

INTRODUCTION

Globally, approximately 39 million people were living with HIV (PLWH) in 2022 [1], of which about two-thirds (25.7 million) were in the African region. The region had the highest number of HIV deaths reported in 2022: 385,300, equivalent to 61.2% of total AIDS-related deaths globally [1]. In Tanzania, the prevalence of HIV is decreasing but still high, with the most recent representative estimate at 4.7% among adults aged 15–49 years in 2017 [2]. In 2023, the country was among five in the African Region reported to have achieved the 95–95–95 targets [1]. However, multiple innovative approaches are needed to ensure all PLWH remain on treatment and virally suppressed.

In Tanzania, delivering HIV services is centred at the facility level. With an increased number of PLWH on ART resulting from the "Universal Test and Treat policy" (UTT) [3] and longer survival due to ART, there is a risk that facilities become overwhelmed and are unable to provide quality services [4]. Evidence on the effectiveness of innovative HIV service provision approaches such as differentiated HIV care models (DCM) is needed, especially in sub-Saharan African where evidence is still building [5–8]. DCM includes different care packages for clients based on their needs and expectations; these packages are tailor-made based on local needs and options, consisting of several building blocks (what, where, who, when; see Table A1) [6, 7, 9, 10]. Two reviews found evidence to suggest decentralised ART distribution leads to similar treatment outcomes, although the quality and quantity of evidence were limited [7, 11]. The client benefits of decentralised models include improved retention in care, improved adherence, reduced travel time, and increase in social support [12]. Apart from the health-related benefits, DCM was also found to be cost-efficient [13] and significantly reduce the workforce needed compared to the facility-based approach [14]. According to a Tanzanian study, this strategy is cost-effective, but the authors advised against concluding it because there was inadequate data on retention [13].

The Tanzanian National Guideline for the Management of HIV/AIDS [15] advocates the establishment of DCM for clients established on ART (referred to as stable on ART) in both facilities and communities; however, the guideline requires that the management of a community-based treatment model be carried out by a trained and certified healthcare worker. However, implementing this seems challenging because of the health staff shortage. It was estimated that the shortage of human resources for health was 52% in 2014 [16]. Any attempt to implement this part of the guideline would mean taking from the already limited available staff of the facilities to run community care. To facilitate the implementation of DCM we piloted a DCM of community-based ART provision in which community health workers (CHW) delivered decentralised HIV services at the community level including drug dispensing in Shinyanga, Tanzania.

We assessed whether our CHW-based DCM model (hereon referred to as CHW-DCM) yielded the same treatment outcomes as stable clients who received care in the health facility (standard of care-SoC). Our primary objective was to compare continued stability in care, and secondary objectives were to compare the risk of loss to follow-up (LTFU) and treatment adherence, all over 18 month follow-up period. The evidence from this study will add to the limited existing knowledge on CHW-led HIV care and will help the Tanzanian Ministry of Health determine how best to implement CHW-DCM in the country.

MATERIALS AND METHODS

Study setting

The Feasibility of Universal Access to HIV Test and Treat project was conducted in two regions of Shinyanga and Simiyu in the northern part of Tanzania, which has been described in detail by de Nardo et al. [17]. The main activities of the project were the implementation of UTT and a CHW-led HIV differentiated care model. Outcomes of the community-based testing component of the project were published by Martelli et al. [18], this paper focuses on the outcomes of the latter intervention. Data for this analysis comes from two project sites, Bugisi and Ngokolo health centres, both from the Shinyanga region, where the piloting of the DCM of community-based ART took place. These sites were chosen for piloting as they represented a rural (Bugisi) and urban (Ngokolo) setting. All HIV care in Tanzania is free of charge to the clients.

Study design and population

This was a prospective cohort study comparing two groups: a cohort of stable clients who received care and treatment from the clubs (referred to as CHW-DCM) and a cohort of stable clients who attended normal clinic visits at the health centres (referred to as SoC). The criteria used to determine the stability of the participants were based on the national guidelines at the time and are found in Table 1. All stable clients in care during the study period were included in the analysis (see Table A1); there was no predetermined sample size.

Implementation of the CHW-DCM began in Bugisi in July 2018, followed by Ngokolo in September 2018. Clients were included in the analysis if they met the criteria during the first 12 months after implementation of the CHW-DCM, to allow for a minimum of 6 months of follow-up time. The maximum follow-up time for this study was 18 months from the baseline date (i.e., July 2018 to January 2020 and September 2018 to March 2020 for Bugisi and Ngokolo respectively).

TABLE 1 Inclusion and exclusion criteria for participants in both CHW-DCM and SoC cohorts. These criteria for clients stable on ART were according to the national guidelines [15].

Inclusion criteria (Stable client)

- Age above 5 years
- Received ART for at least 6 months
- Not on TB treatment
- Have a good understanding of lifelong adherence of 95% and kept clinic visit appointments for the past 6 months
- Average adherence to ART >95% during the last 6 months (as calculated by pill count, using the formula % adherence = 100 − % of pills missed)
- On first-line ART
- Viral load less than 200 copies/mL (last available HVL)

Exclusion criteria (Unstable client)

- Age below 5 years
- Pregnancy
- HVL > 200 copies/mL
- Current ART for less than 6 months
- Presence of active opportunistic infections (including TB) in the past 6 months
- The presence of poorly controlled comorbidities
- Poor adherence to scheduled visits (defined as >1 missed scheduled visit or >1 drug refill through a treatment supporter in the past 6 months)
- Suboptimal adherence to ART (defined as missed ART doses on > = 2 days in a month during the preceding 6 months)

Study intervention: CHW-led differentiated HIV care model (CHW-DCM)

A detailed overview of the study intervention was published by De Nardo et al. [17]. CHW-led community-based HIV care services were provided to a group of stable clients (referred to as clubs, in this paper CHW-DCM), formed in locations close to clients' residences. Clubs were led by a CHW who managed club activities and were overseen by club nurses. During a meeting conducted every 3 months, the CHW screened all clients for TB, briefly checked for any symptoms (fever, weight loss, cough, skin rash), asked after pregnancy, measured weight and BP, provided adherence counselling, health education, and distributed ART drugs. If any of the exclusion criteria as outlined in Table 1 were met, the client was defined as 'unstable' and was referred back to the health facility. CHW also completed the registers which captured the same information as the facility register with additional information specific to the CHW-DCM (see data sources, below), and transferred them back to the facility for data entry. As per the national guidelines, the clients in the CHW-DCM returned to the facility for CD4 measurement and a clinician consultation every 6 months. There were no additional costs to the client for participating in the CHW-DCM.

During the first 6 months of club implementation, club nurses provided mandatory training and close supervision, after which clubs were independently run by the CHW. Club nurses were the main link between the club and health facility and were responsible for following up with the clients referred back from the club. Clients attending clubs were allowed to access the facility anytime they wished to do so. Each club had an elected club leader, chosen from among the clients who, together with CHW, assisted in communicating meeting dates to other members and following up on clients who failed to attend the club meeting. The CHW completed the reason for not being present and communicated this back to the facility through the responsible club nurses. The building blocks detailing differentiated service delivery for this project are shown in the Appendix (Table A1).

Participants enrolment into CHW-DCM

Clients were enrolled into CHW-DCM by clinicians based on the criteria for stable clients as presented in Table 1. All clients attending clinics during their routine clinic visits who met the stability criteria were invited to join CHW-DCM; those who accepted gave informed consent, were referred to the nearest CHW-DCM within their communities, and became part of the intervention group. CHW-DCM participants did not contribute follow-up time to the SoC group before they were enrolled in their CHW-DCM, despite potentially meeting stability criteria at an earlier time point. During the informed consent procedure, staff paid extra attention to confidentiality procedures that were in place to reduce the risk of stigma and disclosure by participating in CHW-DCM.

Control group: Standard of care (SoC)

The SoC group, comprised of all stable clients as defined by the criteria in Table 1 who opted to remain in facility care. This group received no specific intervention except routine care as per national guidelines. Clients attended their routine clinic visits at the health facilities, including two-monthly drug refill visits and a clinician review including CD4 measurements every 6 months.

Data sources

Two data sources were used; (1) routine data on HIV care and treatment (CTC) from the Tanzania National AIDS Control Program (NACP). At health facilities, CTC data were collected in hard copies filled by the clinician at the respective facility and later entered into an electronic database by trained facility data staff. (2) Additional data (not routinely collected for the NACP) on CHW-DCM participants collected by CHW during CHW-DCM visits; which included the date of CHW-DCM enrolment. All clients had identifiers (CTC numbers) captured in both data sources, which made it possible to link the two data sources. During the study period, facilities reported delays in the return of HIV viral load (HVL) results from a zonal laboratory

located in another region; the latest available HVL results were used for this analysis (January 2022).

Details of measurements

Information from CTC database relevant to this study included demographic information such as facility location, date of birth, sex, marital status (married, single, divorced, widowed, or cohabiting), and address (ward, village, street). Clinical information collected at each visit and included in the analysis were CD4 count, ART status (never, start, continue, stop, or restart), WHO clinical staging (stage 1–4), adherence (measured by pill count), HVL in copies/ml and the status of TB screening, and/or medication if on TB treatment. Other information included were dates: date of diagnosis, date enrolled into care at HIV clinic at the health facility (), date of start of ART, visit dates, and the client's status at the clinic (active, lost to follow-up, died, or transferred out).

The clients' baseline information for the CHW-DCM cohort was determined by their clinical and demographic characteristics at the time of joining the CHW-DCM. For the SoC cohort, this was set for July and September 2018 for Bugisi and Ngokolo respectively, if in care and stable (i.e., met inclusion criteria as indicated in Table 1) at that time, or whenever they became stable during the period of 1 year for Bugisi and Ngokolo (up to July and September 2019, respectively).

Study outcomes and definitions

Stability in care was defined as continuing to be stable as per the criteria defined in Table 1. Unstable clients were defined as those who required additional clinical care, adherence support, and switching to second line in case of treatment failure. LTFU was defined as per the national guidelines [19]: not having attended any project facility or CHW-DCM for 90 consecutive days from the last scheduled appointment and not known to be dead or transferred out; this included ART collection visits. For this analysis, the date of LTFU was calculated as the last seen visit date plus 180 days for those with a missing appointment date, or the last appointment date plus 90 days for clients whose appointment date was recorded but was missed. Poor adherence was defined as adherence to less than 95% of ART drugs since the last visit, calculated by pill count method (% adherence = 100 − % of pills missed) ([number of pills remaining divided by the total number of pills prescribed] × 100).

Data analysis

All data were analysed using Stata 15 software. Characteristics of the study clients by service delivery models were described and presented as mean and standard deviation (SD) or median and interquartile range (IQR) for continuous variables. Chi-square tests were used to compare the proportion of stability in care, treatment adherence, and HVL suppression. To compare the proportion of two samples (CHW-DCM vs. SoC), two-sample proportion test was used. Student's *t*-test and Mood's median tests compared the mean age of participants and median time since enrolled into care or start of ART. Uni- and multivariable Cox regression models analysed factors associated with clients becoming unstable, and with the risk of LTFU during the follow-up period. Factors significant at $p = 0.05$ in the univariable model were selected for the multivariable model. Kaplan–Meier curves were plotted to show the probability of being LTFU by CHW-DCM versus SoC.

Ethics approval

The conduct of this study was approved by the National Institute for Medical Research-NIMR(NIMR/HQ/R.8a/Vol. IX/2711), participation in the CHW-DCM was voluntary and informed consent was sought before participation. Permission to access the routine de-identified data on HIV care and treatment was granted by NACP through signed data transfer agreements.

RESULTS

Characteristics of participants

A total of 2472 stable clients were included in the two cohorts: 605 (24.5%) in CHW-DCM and 1867 (75.5%) in SoC, (see Figure A1 for a flow chart). In total, there were forty-six (46) clubs in the study, (33 in Bugisi and 13 in Ngokolo). The cumulative enrolment into the two groups is outlined in Figure 1. Characteristics of study participants by service delivery model are presented in Table 2. Clients receiving CHW-DCM were more often female and older than those in SoC (67.8% Female and mean age 42.8 years versus 63.8% Female and mean age 39.1 years). They had also been in care and on ART for a longer time (median time since starting ART of 3.8 versus 2.6 years for CHW-DCM and SoC respectively).

See Figure A1 for a flow diagram.

Study outcomes

The main outcomes are presented in Table 3. The proportion of clients who became unstable over time was higher among SoC than CHW-DCM (13% vs. 6%), also shown in Figure 2, mainly due to the difference in the

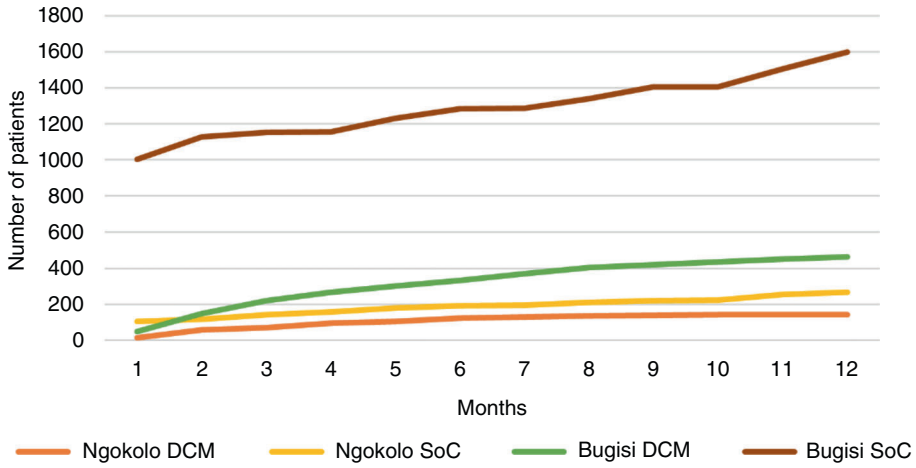

FIGURE 1 Cumulative number of clients enrolled in the CHW-led differentiated care model (CHW-DCM) or standard of care (SoC) in both facilities over time.

TABLE 2 Characteristics of study participants.

Characteristics	CHW-DCM $n = 605$ (24.5%)	SoC $n = 1867$ (75.5%)	Overall $n = 2472$ (100%)	*p*-value
Gender				
Male	195 (32.2)	676 (36.2)	973 (35.0)	0.04
Female	410 (67.8)	1191 (63.8)	1805 (65.0)	
Age at baseline in years (mean [SD])	42.8 (14.0)	37.9 (13.3)	39.1 (13.6)	<0.001
Age (years)				
5–15	30 (5.0)	89 (4.8)	119 (4.8)	<0.001
15–25	21 (3.5)	179 (9.6)	200 (8.1)	
25–50	392 (64.8)	1312 (70.3)	1704 (68.9)	
50 years and above	162 (26.8)	287 (15.4)	4490 (18.2)	
Age at ART initiation in years (mean [SD])	38.6 (14.1)	34.5 (13.3)	35.5 (13.6)	<0.001
Marital status				
Single	129 (21.3)	394 (21.1)	523 (21.2)	0.03
Married/cohabiting	322 (53.2)	1038 (55.6)	1360 (55.0)	
Separated/divorced	34 (5.6)	147 (7.9)	181 (7.3)	
Widow	56 (9.2)	115 (6.2)	171 (6.9)	
Children	32 (5.3)	(5.4)	132 (5.3)	
Missing	32 (5.2)	73 (3.9)	105 (4.2)	
Facility name/residence#				
Ngokolo(urban)	141 (23.3)	275 (14.7)	416 (16.8)	<0.001
Bugisi(rural)	464 (76.7)	1592 (85.3)	2056 (83.2)	
Median time (years) since enrolled in care (IQR)	3.8 (1.9–6.3)	2.7 (1.2–5.2)	2.9 (1.3–5.5)	<0.001
Median time (years) since the start of ART (IQR)	3.7 (1.9–5.9)	2.6 (1.2–4.7)	2.7 (1.2–5.1)	<0.001
Median CD4 at study baseline (IQR)	494 (341–688)	463 (294–685)	471 (305–687)	0.01
Median CD4 at ART start	375 (240–578)	368 (211–572)	370 (218–574)	0.53

Abbreviations: CHW-DCM-community health worker-led differentiated care model; IQR-interquartile range; SD, standard deviation; SoC, standard of care.

proportion with poor adherence (8% vs. 2%); there were no differences in the other causes of becoming unstable (detectable HVL, death, and presumptive or confirmed TB). The proportion of clients with LTFU by the end of the study period (18 months) was 77(3.1%), this was not different between the groups.

TABLE 3 Client stability and LTFU in both groups.

Characteristics	CHW-DCM $n = 605$ (24.5%)	SoC $n = 1867$ (75.5%)	Overall $n = 2472$	*p*-value
Client stability during follow-up				
Number becoming unstable (overall)	34 (5.6)	249 (13.3)	283 (11.4)	<0.001
Specific reasons for instability				
Poor adherence	9 (1.5)	145 (7.8)	154 (6.2)	<0.001
Presumptive TB	9 (1.5)	50 (2.7)	59 (2.4)	0.09
Confirmed TB	2 (0.3)	20 (1.1)	22 (0.9)	0.09
Detectable HVL (HVL > 200/μL)[a]	24 (4.9)	105 (7.4)	129 (6.8)	0.06
Death	11 (1.8)	31 (1.7)	42 (1.7)	0.75
Loss to follow-up (LTFU)				
Number (percentage) LTFU	12 (2.0)	65 (3.5)	77 (3.1)	0.07

Abbreviations: CHW-DCM, community-health worker-led differentiated care model; SoC, standard of care.
[a]Percentages were calculated using a denominator as the number of people with a follow-up viral load result ($n = 487$, 1416, and 1903, respectively).

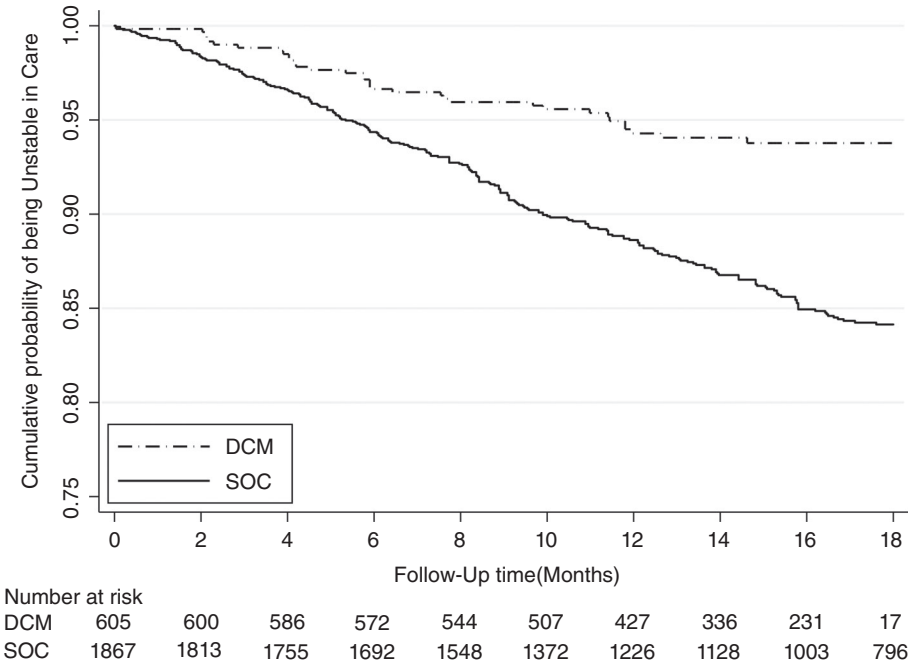

FIGURE 2 The Kaplan–Meier curve for the risk of becoming unstable in care during the study period by service type (DCM and SoC). CHW-DCM, community health worker-led differentiated HIV care model; SoC, standard of care; *p*-value = 0.001.

Factors associated with stability in care and the risk of LTFU

Table 4 presents univariable and multivariable associations with stability in care and risk of LTFU by service model. Clients receiving services via SoC were almost 3 times more likely to be unstable over time than CHW-DCM (adjusted HR 2.68; 95%CI (1.86–3.90)). Females, married clients, and clients receiving services from the rural facility were more likely to remain stable compared to their counterparts. Clients' age was not associated with stability over time.

There was no difference in LTFU between clients receiving CHW-DCM and SoC (HR = 1.54; 95% CI (0.82–2.93)). Clients who were married and/or were on ART for longer were less likely to become LFTU. Clients who had been on ART for more than 3 years were less likely to become LTFU than those less than 1 year on ART (HR = 0.38; 95%CI (0.20–0.71)). The CD4 count at cohort entry was not associated with the risk of LTFU.

TABLE 4 Crude and adjusted hazard ratios for becoming unstable in care and for becoming lost to follow-up by clients' demographics and clinical characteristics.

	Becoming unstable $n = 2472$		LTFU $n = 2472$	
Characteristics	**HR (95% CI)**	**Adjusted HR (95% CI)**	**HR (95% CI)**	**Adjusted HR (95% CI)**
Type of service				
CHW-DCM	**1**	**1**	1	1
SoC	**2.42 (1.69–3.46)**	**2.68 (1.86–3.90)**	1.62 (0.87–3.01)	1.54 (0.82–2.93)
Gender				
Male	1	**1**	1	1
Female	0.81 (0.64–1.02)	**0.72 (0.56–0.93)**	**1.95 (1.14–3.35)**	1.44 (0.82–2.56)
Age				
5–15 years	1.42 (0.85–2.41)	2.18 (0.71–6.72)	0.34 (0.10–1.21)	0.42 (0.05–3.29)
15–25 years	1	1	1	1
25–50 years	**0.68 (0.45–0.99)**	0.72 (0.48–1.09)	**0.44 (0.24–0.80)**	0.61 (0.31–1.18)
50 years and above	0.63 (0.39–1.00)	0.79 (0.47–1.31)	**0.26 (0.11–0.63)**	**0.37 (0.14–0.98)**
Facility location				
Bugisi (rural)	**1**	**1**	**1**	**1**
Ngokolo (urban)	**2.11 (1.62–2.75)**	**2.60 (1.95–3.48)**	**2.50 (1.54–4.04)**	**1.77 (1.02–3.05)**
Marital status				
Married	1	1	1	1
Single	**1.49 (1.11–1.97)**	**1.51 (1.13–2.01)**	2.22 (1.28–3.82)	**2.02 (1.65–3.49)**
Divorced/separated	**2.05 (1.37–3.05)**	**1.92 (1.28–2.88)**	**2.84 (1.34–6.04)**	**2.21 (1.02–4.77)**
Widowed	0.56 (0.28–1.10)	0.63 (0.32–1.27)	**2.40 (1.09–5.26)**	**2.83 (1.23–6.51)**
Child	2.19 (1.44–3.34)	0.87 (0.28–2.68)	1.49 (0.52–4.23)	1.88 (0.28–12.44)
CD4 count at study baseline				
CD4 < 500 cells/mm	1		**1**	1
CD4 > =500 cells/mm	1.05 (0.82–1.33)		**1.64(1.04–2.58)**	1.51(0.93–2.42)
Time since the start of ART				
Less than a year	1	1	1	1
1–3 years	0.72(0.52–1.00)	1.07(0.76–1.52)	**0.48(0.27–0.82)**	0.60(0.33–1.09)
More than 3 years	**0.64(0.46–0.87)**	1.04(0.74–1.48)	**0.29(0.16–0.51)**	**0.38(0.20–0.71)**

Note: Bold values: $p < 0.05$.
Abbreviations: CI, confidence interval, HR, Hazard ratio, LTFU, lost to follow-up.

DISCUSSION

We found that clients attending CHW-led DCM demonstrated better treatment stability and treatment adherence than SoC over 18 months. Additionally, we found there was no difference in the risk of LTFU between the two approaches. CHW-DCM clients were more likely to remain stable than those in SoC over a maximum of 18 months follow-up. The difference in stability in care seemed to be due to poorer adherence among clients in SoC; despite this, the proportion virally suppressed did not differ significantly, however, this may lag behind poor adherence. An important contributing factor to better treatment stability could be more individualised caregiving as reported in a study assessing quality of care in the same study population [20]. The authors of this study reported clients attending CHW-DCM spend almost half the time as those attending SoC, having better access to health providers (CHW), and receiving adequate reminders for appointments and explanations on the benefits of regular use of ART [20].

The absence of risk difference in LTFU between CHW-DCM and SoC in this study suggests the potential of CHW in delivering ART to PLWHA in the CHW-led DCM approach. Other studies found a lower risk of LTFU among clients attending community-based compared to facility-based care [9, 21–23], although this may be explained by differences in the comparator group. For example, facility clients of a Cape Town study [9] included the general ART population including unstable clients as the comparator group, who are more likely to default than our stable clients in SoC. Of note, the proportion of LTFU in our study was low (3.1%), although in the same range as a recent study of outcomes among clients stable on ART in Zambia [24]. These low proportions are likely reflective of a population well established on ART which is evidenced by the high median time on ART in both groups (2.7 years).

Our finding that CHW-DCM clients had better adherence than the SoC clients confirms what was found in previous studies done in sub-Saharan Africa [21, 23, 25], suggesting better adherence among clients receiving community-based compared to facility-based HIV care services. The CHW-DCM was formed within proximity to the clients' residences, lowering the distance to treatment services. We did not have data on the exact difference in distance, but the location of the CHW-DCM ranged between 3 and 35 km from the health facility [20]. Longer distances to health facilities were associated with poor adherence to ART [26]. Community-based care is also generally less crowded than facilities; overcrowding in the facilities with longer waiting hours is associated with poor retention in care [27, 28]. Our findings provide important evidence to suggest the potential of running community-based HIV care led by CHW alongside facility-based services.

To the authors' knowledge, this is the first community-based CHW-DCM study done in a rural district setting in Tanzania where CHW independently ran the DCM and led distribution of ART with support from the facility. Previous studies done in Tanzania used trained nurses or clinicians [29]. There have been a number of CHW-led HIV care initiatives: CHW-led distribution of ART to stable clients done individually in clients' homes [29–31]. While it was feasible to deliver ART to individual homes in the urban city [30, 31], this approach may not be practically feasible in a rural setting where the road infrastructure is poor, houses are scattered, and the mobile network is limited. In contrast to our study, a study in Dar es Salaam [31] restricted their DCM intervention to clients living in the neighbourhood of the facilities; however, with perceived fear and stigma [32] some people accessing services would come far from the facilities within the catchment area. Our evidence on successfully piloting the implementation of a CHW-DCM model in a rural district has the potential to reach a large number of PLWHIV in care if scaled up, as 70% of people in Tanzania live in rural areas [33]. Piloting CHW-led DCM in a country where CHWs are not allowed to dispense drugs provides a unique insight and will hopefully stimulate the discussion around and facilitate change of current guidelines.

This study has several limitations. There was a lack of ability to differentiate within the SoC group between the participants who had not yet been offered CHW-DCM and those who had opted out. It is imaginable that these participants might differ in their risk of LTFU; however, there are various reasons for opting out (distance, stigma, convenience) that make the effect of this selection bias difficult to predict. Another limitation includes concern about disclosure in community-based care also: despite staff training regarding confidentiality in CHW-DCM, clients who would not want to reveal their HIV status to the community may hesitate to participate leading to selection bias towards those with HIV status already known to the community or who have no fear to disclose. Fear of being recognised when participating in CHW-DCM has been reported previously [22]. Recent qualitative data in the same region showed the opposite for some people: they preferred the anonymity of CHW-DCM versus crowded facility [20].

The project reported missing HVL results from government testing sites. However, this was not different between the two groups, which makes it unlikely that our conclusions regarding viral suppression were affected. Other important limitations include the relatively short follow-up time, 18 months may not be enough to detect the development of viral failure, especially if HVL is not performed frequently.

CONCLUSION

The results from this study among a population well established on ART show the care provided by the CHW-DCM model was equal to, if not better than, care provided in the SoC. These findings provide evidence of the potential of CHW in delivering HIV services while maintaining the same or higher level of desired treatment outcome as that of facility-based clients. This could lead to recognition and integration of CHW in the healthcare system and national guidelines, and continued opportunities for training on subject-specific to enhance their skills beyond formal training. These findings could be used to extend this CHW-DCM model to similar settings.

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CONFLICT OF INTEREST STATEMENT

The authors have declared no conflicts of interest.

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APPENDIX A

TABLE A1 Differentiated service delivery building blocks of the CHW-DCM model implemented.

Who	*What*
Clinician, nurse (club nurse), community health worker-CHW (club responsible) and expert client (club leader)	PLWHIV attending routine care and treatment at project facilities are assessed by a clinician for inclusion (stable clients and consented) into community-based care (clubs) formed by clients residing from the same community
	Routine club activities include ART drug refill; adherence assessment and counselling; counselling on index testing; health education; TB screening and provisional referrals
When	*Where*
Quarterly—Every 3 months	Community-based, in locations close to clients' residences

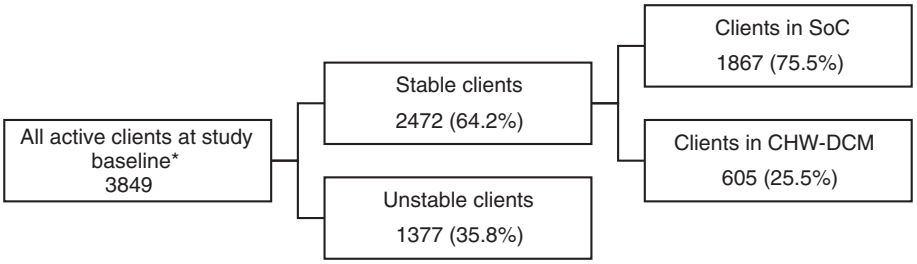

FIGURE A1 Flow chart of enrolment of participants. *Study baseline was the start of the CHW-DCM, July 2018 for Bugisi and September 2018 for Ngokolo Health Centres, respectively. CHW-DCM, community-health worker-led differentiated care model; SoC, standard of care.