Integrated community-based HIV+NCD care in microfinance groups in Kenya: Results from the Harambee cluster randomized trial

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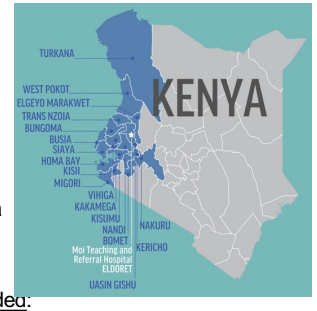
BACKGROUND

The **Harambee** cluster randomized trial tested a differentiated care model for HIV, diabetes and hypertension within community microfinance (MF) groups of people living with HIV (PLHIV) in rural Kenya. The hypothesis was that integrating community-based HIV and non-communicable disease (NCD) care with group microfinance would improve viral suppression among PLHIV by alleviating barriers related to distance to health facilities, inefficient vertical care delivery, and socioeconomic factors.

METHODS

Fifty-seven microfinance groups of PLHIV, ≥18 years of age, were randomized in a 1:1 ratio to receive integrated community-based (ICB) care or standard facility-based care (SOC) in Busia and Trans Nzoia Counties in western Kenya (**Fig. 1**).

Fig. 1: Study catchment area



The ICB intervention included:

(1) clinical care visits during MF group meetings inclusive of NCD management, distribution of antiretroviral therapy (ART) and NCD medications; health education;
(2) support for ART adherence; and
(3) facility referrals as needed.

Primary outcome: Effectiveness was estimated as the difference in HIV viral suppression (RNA <400 cp/mL or RNA <200 cp/mL)* at 18 months between the trial arms using a doubly robust generalized estimating equation with a logit link function accounting for dropout. The primary outcome from both trial arms was compared to an additional n=300 age-, sex-, county- and facility-propensity-matched controls receiving facility care alone.

*Before January 1, 2023, 18-month viral suppression was <400 cp/mL. On or after January 1, 2023, viral suppression was <200 cp/mL following 2022 updates to Kenya HIV Prevention and Treatment Guidelines.

Viral suppression increased over 18 months in microfinance groups receiving integrated community-based care (MF+ICB) (OR: 2.16, 95% CI [1.48, 3.19], p< 0.001) and in microfinance groups receiving facility care (MF+SOC) (OR: 1.42, 95% CI [1.05, 1.92], p= 0.023), compared to matched facility care patients without microfinance (Figure 3).

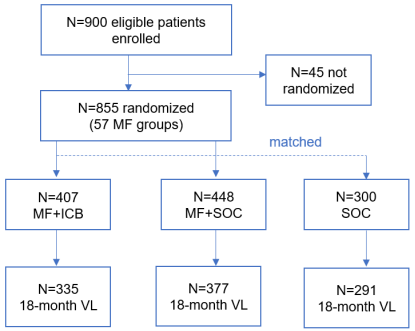
DATA COLLECTION PERIOD

Enrollment: November 2020 – January 2022
Follow up: March 2021 – September 2023

RESULTS

A total of 1,155 participants were enrolled and provided follow up data: 855 microfinance group members were randomized and 300 standard care patients were matched on age, sex, county, and health facility (**Fig. 2**).

Fig 2: Trial enrollment and follow up



On average at baseline, patients were 51.8 years old and 75% were female (**Table 1**). Nearly half (47%) of participants earned less than 5000 Kenyan Shillings (~$35 USD) per month.

Table 1: Characteristics of study population at baseline stratified by study arm.

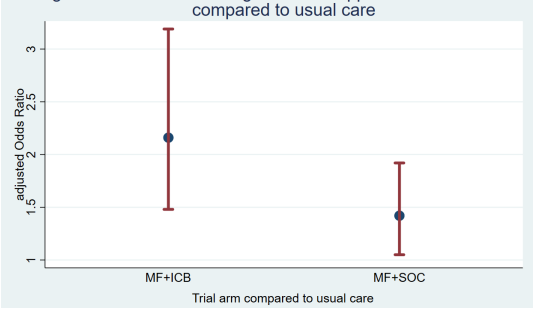
	MF+ICB N=407	MF+SOC N=448	SOC N=300	Total N=1155	P value
Age, mean, in years (SD)	51.7 (11)	51.4 (12)	52.6 (11)	51.8 (11)	0.36
	n (%)	n (%)	n (%)	n (%)	
Female	305 (75)	335 (75)	230 (77)	871 (75)	0.84
Marital status = married[1]	167 (41)	211 (47)	126 (42)	504 (44)	0.16
Monthly income <5000 KES	134 (44)	156 (45)	152 (52)	442 (47)	0.10
Educational attainment					0.02
None	52 (13)	81 (18)	49 (16)	182 (16)	
Primary	211 (52)	237 (53)	164 (55)	612 (53)	
Secondary	53 (13)	47 (11)	59 (20)	159 (14)	
Other[2]	35 (9)	25 (6)	28 (9)	88 (8)	
Viral suppression (<400 cp/mL)	384 (94)	415 (93)	291 (97)	1090 (94)	0.28

MF: microfinance; ICB: Integrated Community-Based Care; SOC: standard of care; SD: standard deviation
[1]Non-married marital status options: widowed, never married, divorced/separated, other, missing; [2]Other educational attainment: tertiary, missing

RESULTS

There was no intervention effect on 18-month viral suppression when comparing MF+ICB to MF+SOC (OR: 1.20, 95% CI [0.90, 1.60], p = 0.23).

Figure 3: Odds of achieving HIV viral suppression at 18-months compared to usual care



CONCLUSIONS

- Among microfinance groups, those who received integrated HIV+NCD care did not have statistically higher viral suppression compared to SOC. This may be due to high viral suppression at baseline in both arms.
- Formal mediation analyses are needed.
- Improvements in viral suppression among MF group participants compared to matched usual care patients suggests that differentiated HIV care models may be more effective if they can mitigate socioeconomic barriers to care engagement.

ADDITIONAL KEY INFORMATION

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