



**Combining community-based chronic disease care with economic strengthening opportunities for adults living with HIV:
Clustered randomized trial evidence from Kenya**

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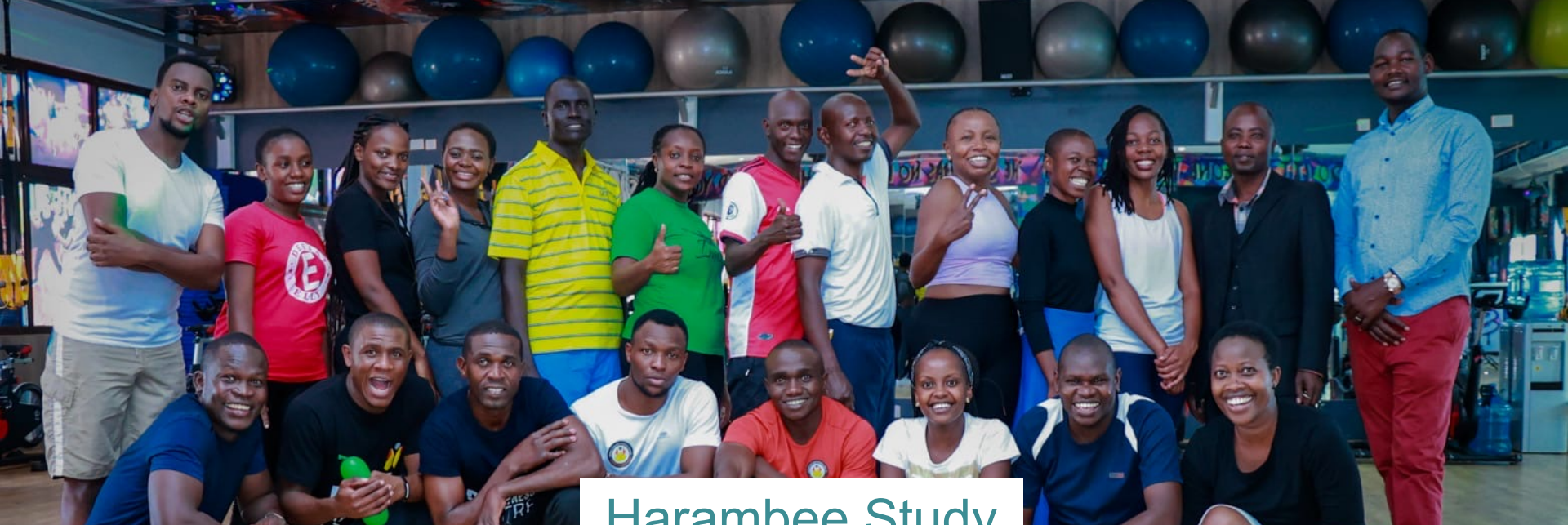


Harambee Study Investigative Team



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Harambee Study



Team





Presentation Outline

- Overview and rationale for the *Harambee* trial
- Methods
- Findings
- Key Messages and Next Steps

The Harambee trial cluster randomized trial

Trial registration
number: [NCT04417127](https://www.clinicaltrials.gov/ct2/show/study?term=NCT04417127)

Open access

Protocol

BMJ Open Integrated community-based HIV and non-communicable disease care within microfinance groups in Kenya: study protocol for the Harambee cluster randomised trial

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ABSTRACT

Introduction In Kenya, distance to health facilities, inefficient vertical care delivery and limited financial means are barriers to retention in HIV care. Furthermore, the increasing burden of non-communicable diseases (NCDs) among people living with HIV complicates chronic disease treatment and strains traditional care delivery models. Potential strategies for improving HIV/NCD treatment outcomes are differentiated care, community-based care and microfinance (MF).

Methods and analysis We will use a cluster randomised trial to evaluate integrated community-based (ICB) care incorporated into MF groups in medium and high HIV prevalence areas in western Kenya. We will conduct baseline assessments with n=900 HIV positive members of 40 existing MF groups. Group clusters will be randomised to receive either (1) ICB or (2) standard of care (SOC). The ICB intervention will include: (1) clinical care visits during MF group meetings inclusive of medical consultations, NCD management, distribution of antiretroviral therapy (ART) and NCD medications, and point-of-care laboratory testing; (2) peer support for ART adherence and (3) facility referrals as needed. MF groups randomised to SOC will receive regularly scheduled care at a health facility. Findings from the two trial arms will be compared with follow-up data from n=300 matched controls. The primary outcome will be VS at 18 months. Secondary outcomes will be retention in care, absolute mean change in systolic blood pressure and absolute mean change in HbA1c level at 18 months. We will use mediation analysis to evaluate mechanisms through which MF and ICB care impact outcomes and analyse incremental cost-effectiveness of the intervention in terms of cost per HIV suppressed person-time, cost per patient retained in care and cost per disability-adjusted life-year saved.

Ethics and dissemination The Moi University Institutional Research and Ethics Committee approved this study (IREC#0003054). We will share data via the Brown University Digital Repository and disseminate findings via publication.

Trial registration number NCT04417127.

Strengths and limitations of this study

- First randomised controlled trial (RCT) to evaluate the impact of integrating HIV/non-communicable diseases care within group microfinance on viral suppression and retention in care.
- The cluster randomised design allows the effect of integrated community-based care to be differentiated from that of group microfinance and standard of care.
- The study will enrol patients regardless of viral suppression status, thereby reaching some of the highest-risk populations who are often excluded from other differentiated care models.
- The exclusion of HIV-negative participants limits the generalisability of study findings to groups that may otherwise benefit from community-based care and microfinance but protects the privacy and confidentiality of people living with HIV.

INTRODUCTION

Despite considerable advances in expanding access to antiretroviral therapy (ART) in sub-Saharan Africa (SSA) over the past decade, retention in HIV care remains suboptimal: only half of people living with HIV (PLHIV) in SSA are virally suppressed.^{1–3} In western Kenya, the primary barriers to retention in HIV care are distance to health facilities, inefficient vertical care delivery and limited means for accessing transportation and food.^{4–6} Access barriers are heightened in remote locations where travel is restricted and transportation fees are prohibitively high relative to income.⁷ Such barriers lead to gaps in ART adherence and eventual unsuppressed viral load (VL), which allows for disease progression and greater risk of transmission.⁸ The

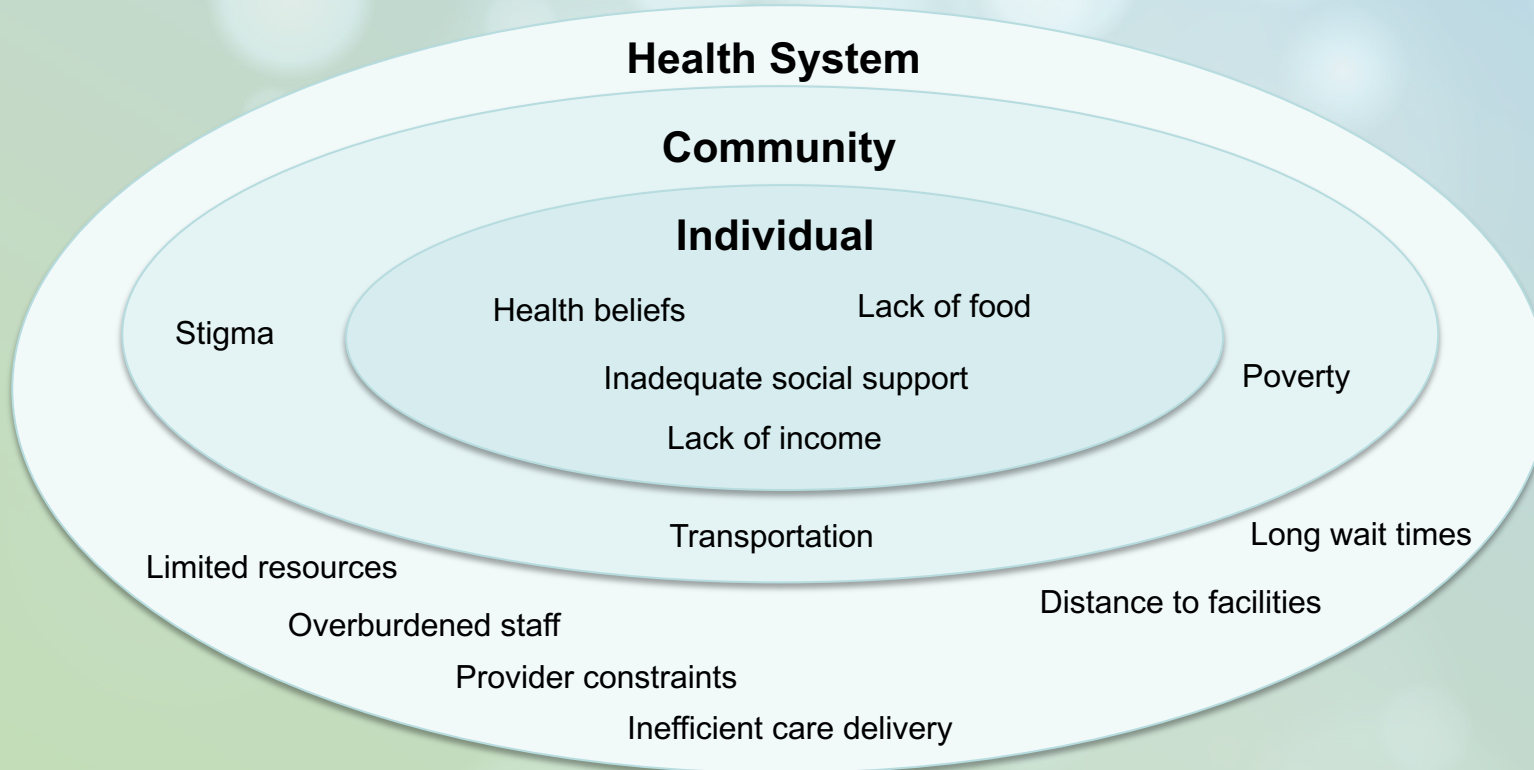
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Our goal is to test the hypothesis that providing integrated HIV and non-communicable disease care within community microfinance groups will improve viral suppression and retention among PLHIV in Kenya via two mechanisms: improved household economic status and easier access to care.



Persistent multilevel barriers to engagement in HIV care cascade



Wachira J, Naanyu V, Genberg B, Koech B, Akinyi J, Kamene R, Ndege S, Siika AM, Kimayo S, Braitstein P. **Health facility barriers to HIV linkage and retention in Western Kenya.** *BMC Health Serv Res.* 2014 Dec 19;14:646

Rachlis B, Naanyu V, Wachira J, Genberg B, Koech B, Kamene R, Akinyi J, Braitstein P. **Identifying common barriers and facilitators to linkage and retention in chronic disease care in western Kenya.** *BMC Public Health* 2016;16:741.


Fox MP, Rosen S. **Retention of adult patients on antiretroviral therapy in low- and middle-income countries.** *JAIDS* 2015;69:98–108.



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Impact of Bridging Income Generation with Group Integrated Care (BIGPIC) on Hypertension and Diabetes in Rural Western Kenya

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[Journal of General Internal Medicine](#) **32**, 540–548 (2017) | [Cite this article](#)

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Thus, the specific aims of *Harambee* are to:

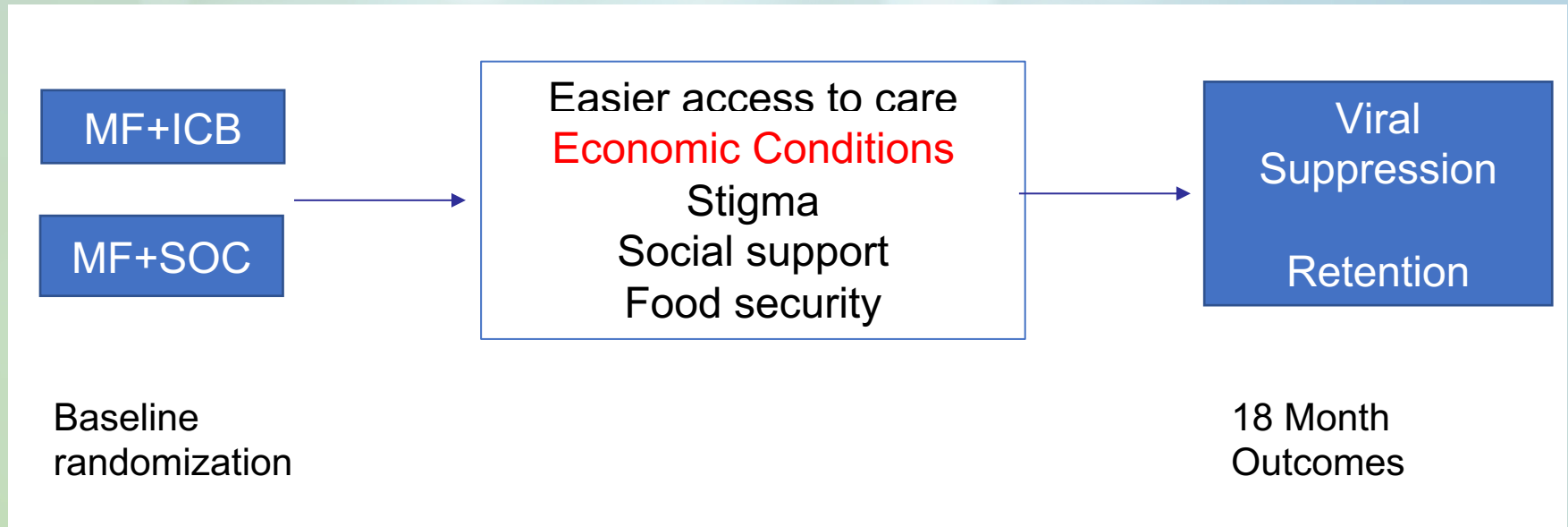
Aim 1: Evaluate the extent to which integrated community-based HIV care with group microfinance affects viral suppression and retention in care among PLHIV in rural western Kenya;

Aim 2: Identify the specific mechanisms through which microfinance and integrated community-based (ICB) care impact viral suppression; and

Aim 3: Estimate the cost-effectiveness of the intervention relative to SOC with and without microfinance in terms of (1) cost per HIV suppressed person-time, (2) cost per patient retained in HIV/NCD care and (3) cost per DALY averted.

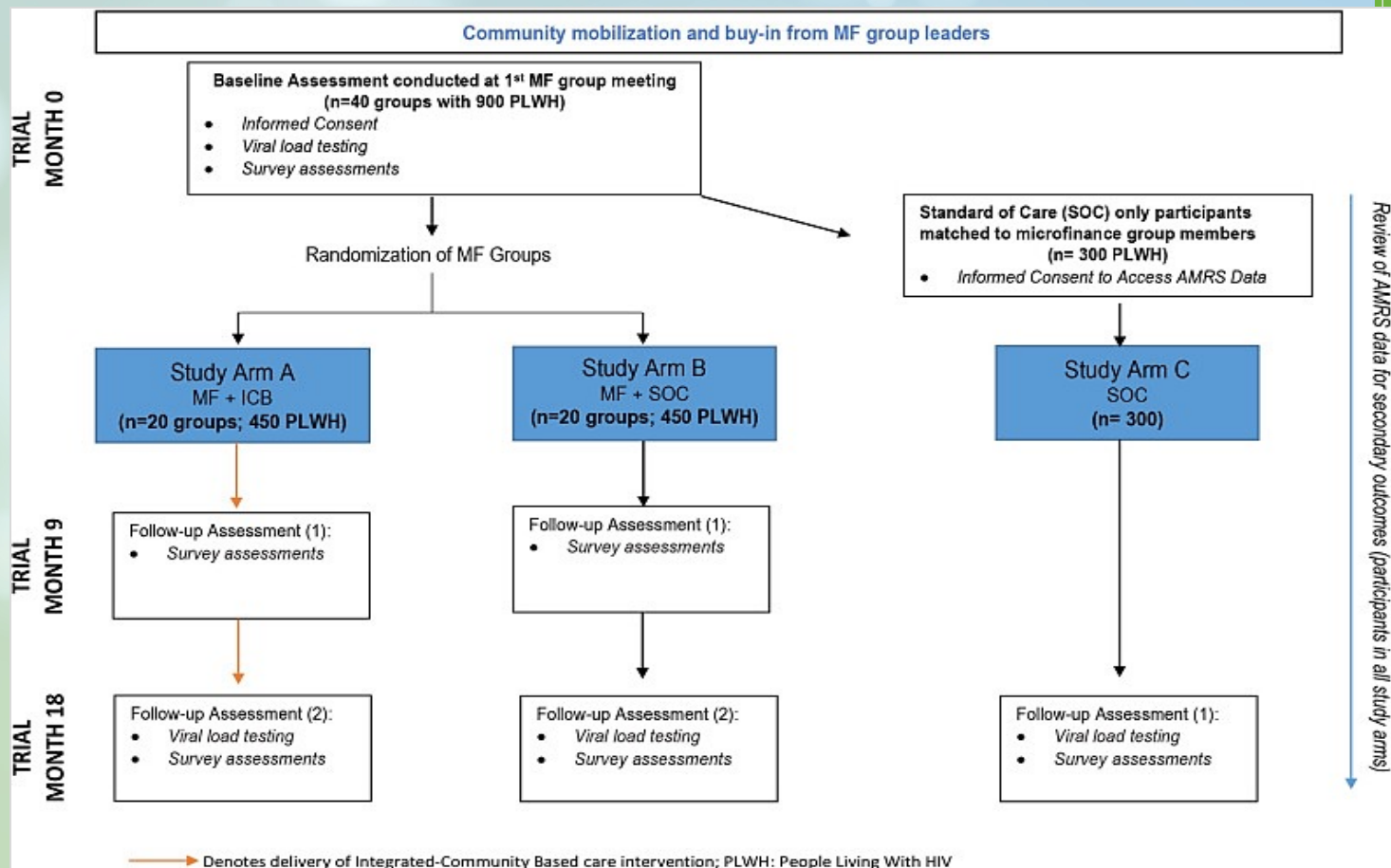


Aim 2: Identify the specific mechanisms through which microfinance and integrated community-based (ICB) care impact viral suppression; and





Methods – Study Design





Methods – Analytic Approach

- **Data collection:** every 3 months for 18 months during microfinance group meetings
- **Regression Analysis:** $y_i = \alpha + \beta D_i^{intervention} + X_i' \theta + \varepsilon_i$
- **Primary outcomes** (y_i):
 - (1) Amount spent on purchasing microfinance shares
 - (2) Amount of outstanding loan debt
- **Independent variable** ($D_i^{intervention}$) : integrated, community-based HIV/NCD care (1=yes, 0 = no)
- **Covariates** ($X_i' \theta$): age, gender (male =1, female =2), highest education level completed (1=None, 2=Primary, 3=Secondary, 4=Tertiary), household hunger (1 = low to no hunger, 2 = moderate hunger, 3 = severe hunger)
- **Treatment-by-time interaction**



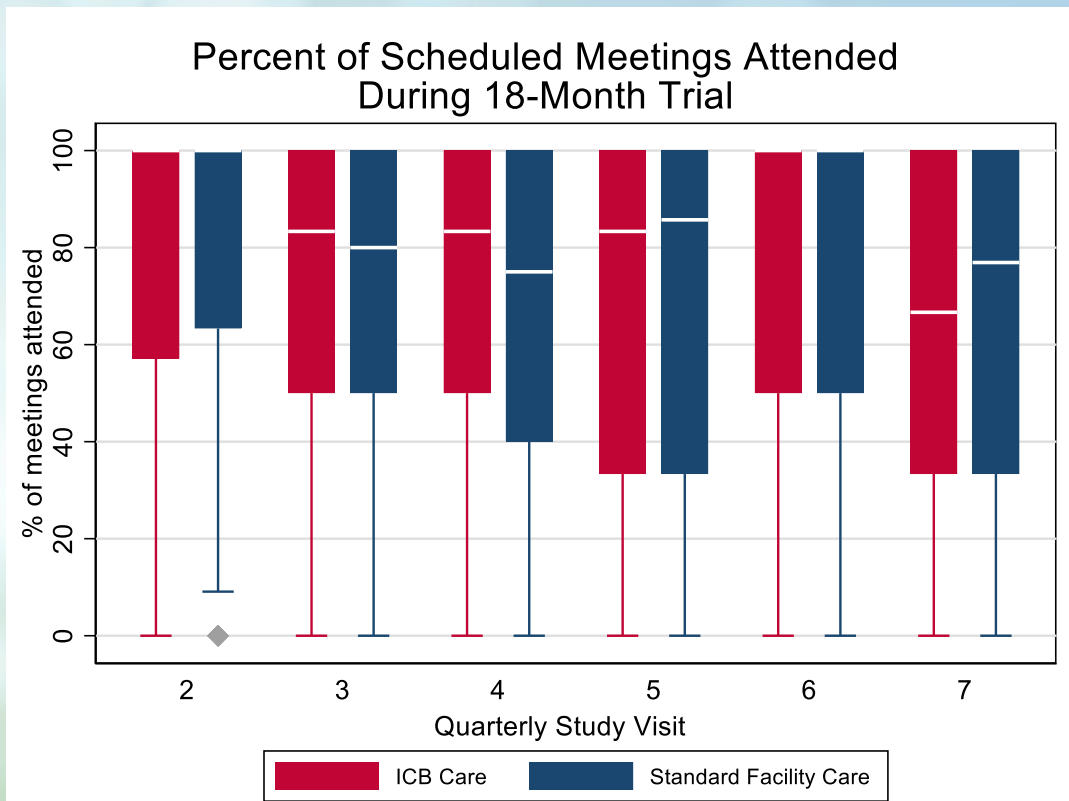
Characteristics of microfinance groups at first study visit post randomization

| | Total | Receiving integrated, community-based care | Receiving standard, facility-based care | p-value |
|--|--------------|--|---|---------|
| Individual characteristics | N=742 | N=351 | N=391 | |
| Female (%) | 74.5 | 73.5 | 75.4 | 0.54 |
| Mean age in years (SD) | 50.67 (11.3) | 50.77 (11.1) | 50.57 (11.6) | 0.82 |
| Highest education completed = primary school (%) | 78.3 | 74.9 | 81.3 | 0.07 |
| Moderate to severe household hunger (%) | 66.3 | 62.1 | 70.1 | 0.02 |
| Monthly income < 5,000 KSH (%) | 39.1 | 38.2 | 39.9 | 0.18 |
| Mean months participating in GISHE (SD) | 62.37 (63.4) | 63.68 (64.9) | 61.18 (62.0) | 0.59 |
| Group characteristics | N=57 | N=29 | N=28 | |
| Mean No. of active group members (SD) | 16.34 (6.5) | 15.74 (6.3) | 16.88 (6.7) | 0.02 |
| Frequency of group meetings (%) | | | | <0.001 |
| Weekly | 15.0 | 17.7 | 12.5 | |
| Bi-Monthly | 48.2 | 33.9 | 61.1 | |
| Monthly | 36.8 | 48.4 | 26.3 | |

Data are presented as mean (SD) for continuous measures, and % (n) for categorical measures. For continuous variables, a two sample t-test was used to compare differences between groups; for categorical variables, a Pearson's chi-squared test was used. GISHE: group integrated savings for health empowerment, KSH: Kenyan Shillings

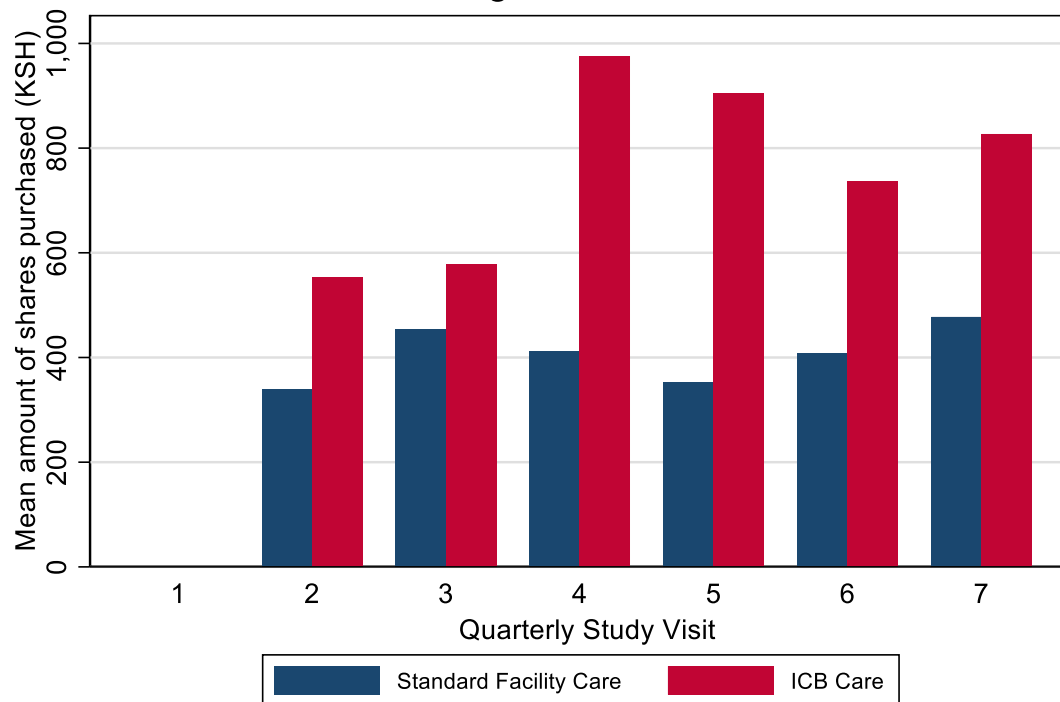


| | Meetings Scheduled Per Quarter | | Meetings Attended Per Quarter | |
|--|--------------------------------|---|-------------------------------|---|
| | Mean (SD) | Median (25 th , 75 th) | Mean (SD) | Median (25 th , 75 th) |
| Integrated Community-Based Care | 5.9 (3.6) | 6.0 (3, 6) | 4.1 (3.2) | 3.0 (2, 6) |
| Standard Facility Care | 5.2 (2.7) | 6.0 (3, 6) | 3.5 (2.5) | 3.0 (2, 5) |





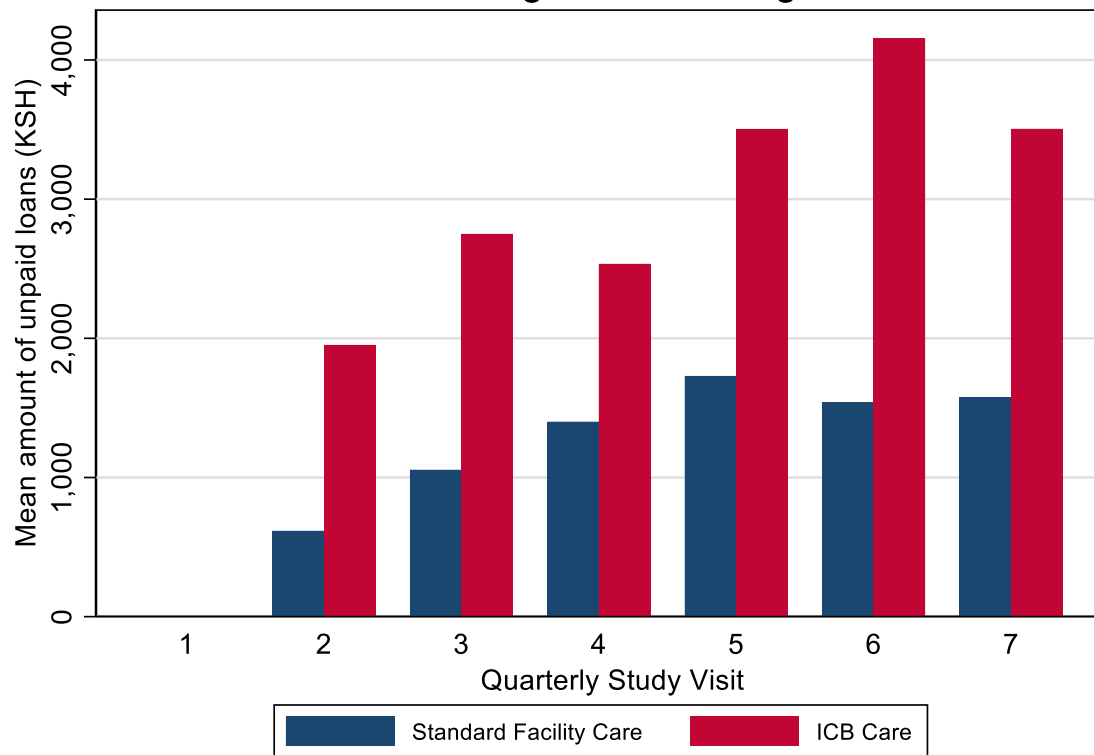
Amount of Microfinance Shares Purchased During 18-Month Trial



| | Shares Purchased Per Quarter (KSH)* | |
|--|-------------------------------------|---|
| | Mean (SD) | Median (25 th , 75 th) |
| Integrated Community-Based Care | 760 (1503) | 250 (100, 650) |
| Standard Facility Care | 406 (870) | 200 (80, 400) |
| *p<0.05 | | |



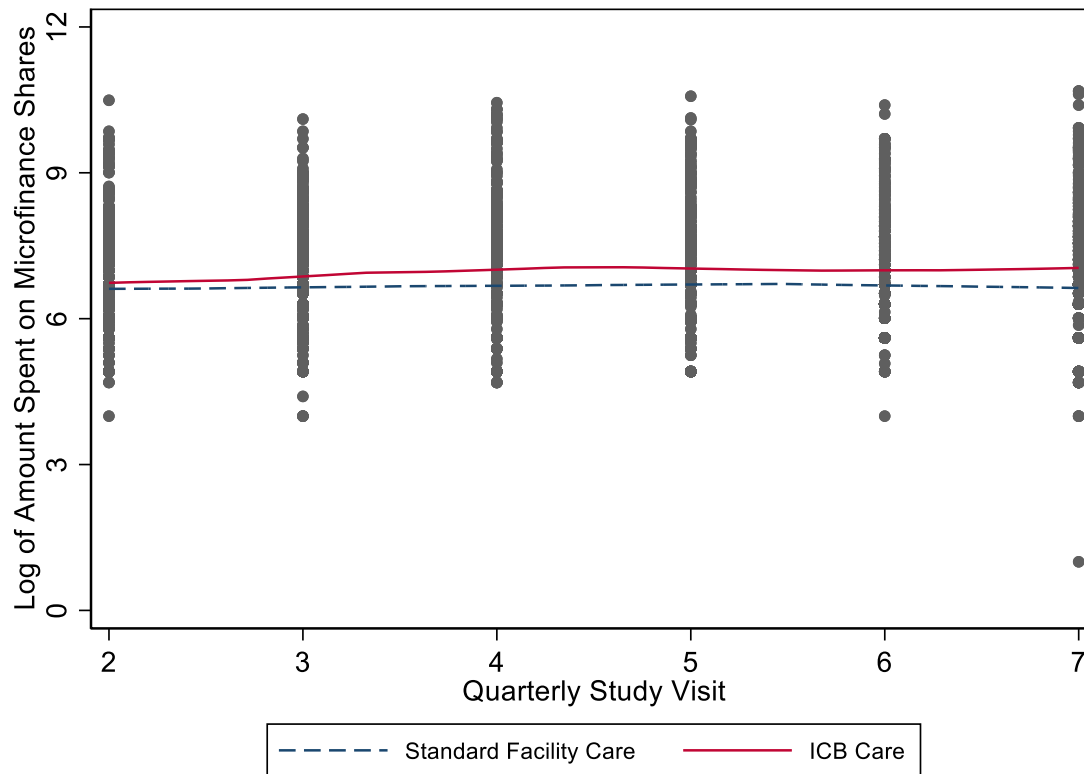
Amount of Outstanding Loans During 18-Month Trial



| | Proportion defaulted on loans during last quarter (95% CI) | |
|---|---|-------------------------|
| | Visit 4 (Month 9) | Visit 7 (Month 18)* |
| Integrated Community-Based Care | 0.045 (0.027, 0.074) | 0.071 (0.047, 0.104) |
| Standard Facility Care | 0.040 (0.024, 0.065) | 0.116 (0.087, 0.153) |
| *p<0.05 at Visit 7 but not significant at Visit 4 | | |



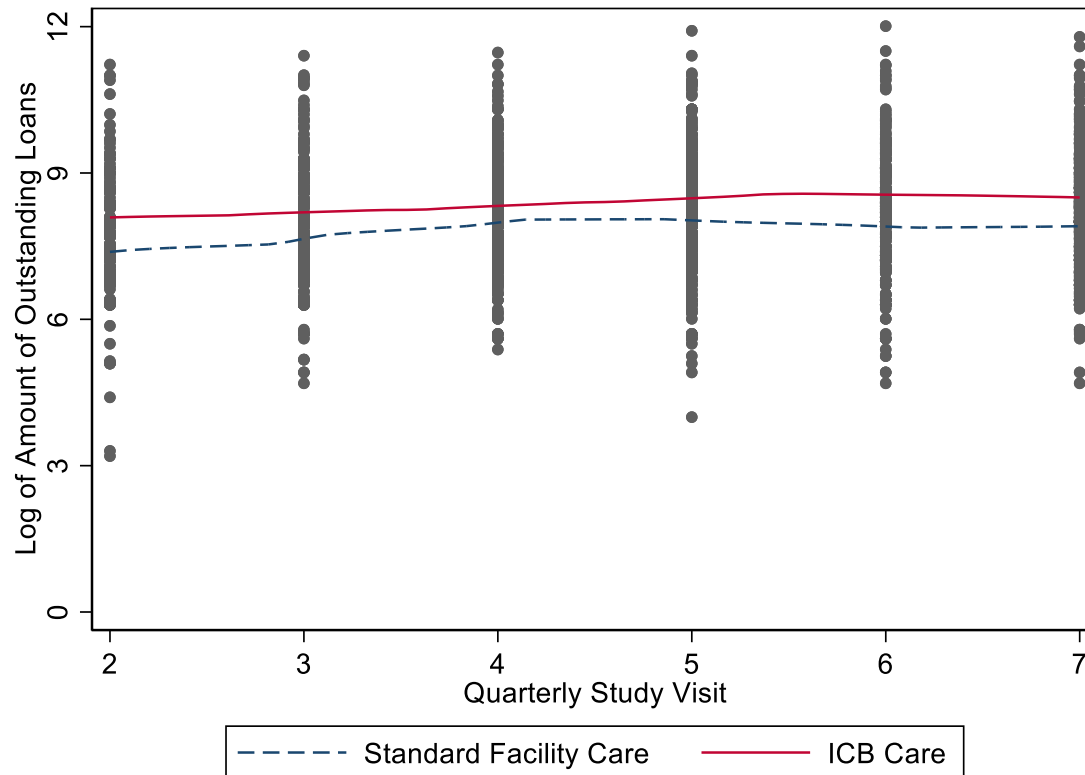
Time-by-intervention interaction regression



P = 0.033;
models
adjusted for
age, gender,
education
level,
household
hunger



Time-by-intervention interaction regression



$P < 0.001$;
models
adjusted for
age, gender,
education
level,
household
hunger



Key messages

- Quarterly meeting attendance did not statistically significantly differ by trial arm
- Having access to integrated HIV and NCD care within community-based microfinance groups was associated with modest increases in income-generation via microcredit purchases, and with some reductions in loan debt.
- After 9-months, loan debt reductions among intervention recipients began to wane.

Next steps

- Short term:
 - Consider alternative measures of wealth / poverty reduction
 - Are income generation and improved economic conditions mechanisms for improved chronic disease outcomes?
- Medium term:
 - Community-based microfinance groups as a platform for testing other differentiated care delivery models



Thank you!

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