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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Presentation Outline

- Overview and rationale for the Harambee trial
- Methods
- Findings
- Key Messages and Next Steps
Integrated community-based HIV and non-communicable disease care within microfinance groups in Kenya: study protocol for the Harambee cluster randomized 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 access to traditional care delivery models. Potential strategies to improving HIV/NCD treatment outcomes are different care, community-based care and microfinance (MF).

Methods and analysis: We will use a cluster randomised trial to evaluate the impact of integrated community-based care delivered through MF groups incorporating NCDs care, as compared to standard of care (SOC). MF groups will be randomised to receive either an intensive (IC) or a standard (SC) intervention. The IC intervention will include: 1) clinical care visits during MF group meetings; 2) medical consultations; 3) NCD management; 4) adherence education therapy (ART); and 5) point-of-care testing. Primary outcomes are ART adherence and NCD outcomes.

Strengths and limitations of this study: The cluster randomised design allows the effect of integrated community-based care to be differentiated from that of group microfinance and standard of care.

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.

Trial registration number: NCT04417127
Persistent multilevel barriers to engagement in HIV care cascade

Health System

Community

Individual

Stigma

Health beliefs

Lack of food

Inadequate social support

Lack of income

Transportation

Long wait times

Limited resources

Overburdened staff

Provider constraints

Inefficient care delivery

Distance to facilities

Poverty


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

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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

Baseline randomization

MF+ICB

Easier access to care
- Economic Conditions
- Stigma
- Social support
- Food security

MF+SOC

Viral Suppression

Retention

18 Month Outcomes
Methods – Study Design

**Community mobilization and buy-in from MF group leaders**

Baseline Assessment conducted at 1st MF group meeting (n=40 groups with 900 PLWH)
- Informed Consent
- Viral load testing
- Survey assessments

Randomization of MF Groups

**Study Arm A**
MF + ICB
(n=20 groups; 450 PLWH)

Follow-up Assessment (1):
- Survey assessments

Follow-up Assessment (2):
- Viral load testing
- Survey assessments

**Study Arm B**
MF + SOC
(n=20 groups; 450 PLWH)

Follow-up Assessment (1):
- Survey assessments

Follow-up Assessment (2):
- Viral load testing
- Survey assessments

**Study Arm C**
SOC
(n=390)

Standard of Care (SOC) only participants matched to microfinance group members (n=300 PLWH)
- Informed Consent to Access AMRS Data

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Denotes delivery of Integrated-Community Based care intervention; PLWH: People Living With HIV
Methods – Analytic Approach

• **Data collection:** every 3 months for 18 months during microfinance group meetings

• **Regression Analysis:**
  \[ y_i = \alpha + \beta D_{i, \text{intervention}} + X'_i \theta + \epsilon_i \]

• **Primary outcomes** \((y_i)\):
  1. Amount spent on purchasing microfinance shares
  2. Amount of outstanding loan debt

• **Independent variable** \((D_{i, \text{intervention}})\): 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

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

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.
<table>
<thead>
<tr>
<th></th>
<th>Meetings Scheduled Per Quarter</th>
<th>Meetings Attended Per Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>Median (25th, 75th)</td>
<td>Median (25th, 75th)</td>
</tr>
<tr>
<td>Integrated Community-Based Care</td>
<td>5.9 (3.6)</td>
<td>4.1 (3.2)</td>
</tr>
<tr>
<td></td>
<td>6.0 (3.6)</td>
<td>3.0 (2.6)</td>
</tr>
<tr>
<td>Standard Facility Care</td>
<td>5.2 (2.7)</td>
<td>3.5 (2.5)</td>
</tr>
<tr>
<td></td>
<td>6.0 (3.6)</td>
<td>3.0 (2.5)</td>
</tr>
</tbody>
</table>

**Percent of Scheduled Meetings Attended During 18-Month Trial**

- **Integrated Community-Based Care**
  - Mean: 5.9 (SD: 3.6)
  - Median: 6.0 (25th to 75th: 3.6)
- **Standard Facility Care**
  - Mean: 5.2 (SD: 2.7)
  - Median: 6.0 (25th to 75th: 3.6)
### Amount of Microfinance Shares Purchased During 18-Month Trial

<table>
<thead>
<tr>
<th></th>
<th>Shares Purchased Per Quarter (KSH)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Integrated Community-Based Care</td>
<td>760 (1503)</td>
</tr>
<tr>
<td>Standard Facility Care</td>
<td>406 (870)</td>
</tr>
</tbody>
</table>

*p<0.05

![Graph showing the amount of microfinance shares purchased per quarter. The graph displays data for Integrated Community-Based Care and Standard Facility Care. The mean and median values are provided for each category.](#ADHERENCE2023)
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:
  o Consider alternative measures of wealth / poverty reduction
  o Are income generation and improved economic conditions mechanisms for improved chronic disease outcomes?

• Medium term:
  o Community-based microfinance groups as a platform for testing other differentiated care delivery models
Thank you!
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