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Annual clinic visits and extended ART refills in different DSD models for HIV treatment: implementation research experience from Lesotho and Zimbabwe

What's new in DSD for HIV treatment: from WHO recommendations to reality

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Background

- Differentiated service delivery (DSD) models provide flexibility for clients accessing antiretroviral treatment (ART) in sub-Saharan Africa, and decongest healthcare facilities.

- Multimonth dispensing of ART (MMD) is a DSD model that extends the intervals of ART refills up to 6 monthly, in order to limit facility visits for stable ART clients.

- In the COVID-19 era, reducing facility visit frequency and enabling ART receipt outside of health facilities are crucial DSD adaptations to safeguard both ART patients and healthcare workers from coronavirus infection.

- Safely scaling-up MMD to as great a number of ART patients as possible in resource-limited settings with high HIV prevalence is a priority for health systems facing the triple pandemics of HIV, COVID-19 and tuberculosis.

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Overview of the studies

- Limited randomized evidence regarding the safety and effectiveness of out-of facility MMD from resource-limited settings, particularly regarding out-of-facility 6 monthly MMD with annual clinical consultations.
- WHO currently recommends clinical consultations be offered 3-6 monthly for those established on ART
- Two cluster-randomized trials comparing community-based three and six-monthly MMD of ART versus standard-of-care facility-based 3 monthly ART delivery for stable PLHIV.
- Clinical consultations provided 12 monthly at facilities in intervention arms.
- Performed in Lesotho and Zimbabwe in 8 districts
- Outcomes: Retention, viral suppression; cost-effectiveness, and qualitative enquiry was conducted.

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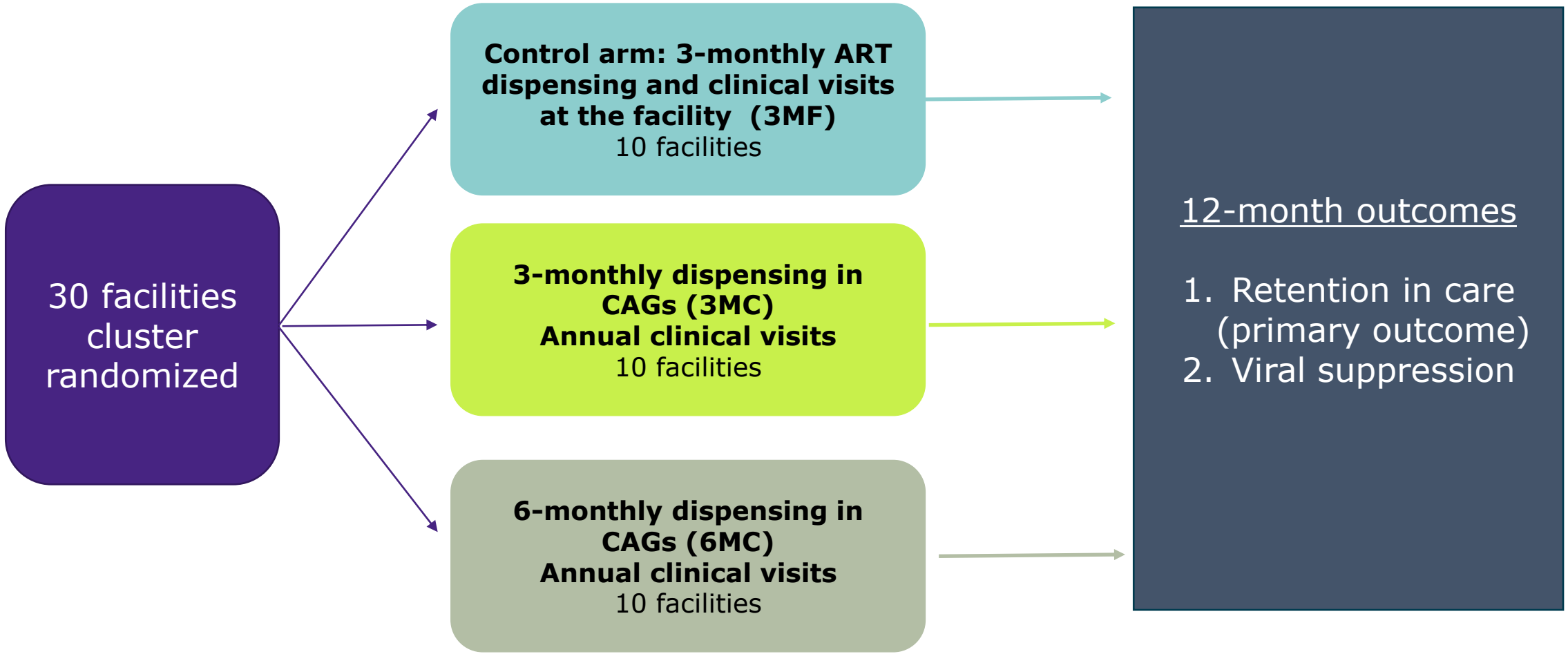
Design and methods



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Description of arms

	3MF (standard of care; control)	Arm 3MC	Arm 6MC
Frequency of ART refills	3 monthly	3 monthly	6 monthly
Frequency of clinical consultations	3 monthly	12 monthly	12 monthly
Location of ART refills	Facility	Community ART group	Community ART group (Zim). Community distribution point (Les)
No. of people in the model per country	1898 Lesotho 1919 Zimbabwe	1558 Lesotho 1335 Zimbabwe	1880 Lesotho 1546 Zimbabwe
No. of sites	10 Lesotho 10 Zimbabwe	10 Lesotho 10 Zimbabwe	10 Lesotho 10 Zimbabwe

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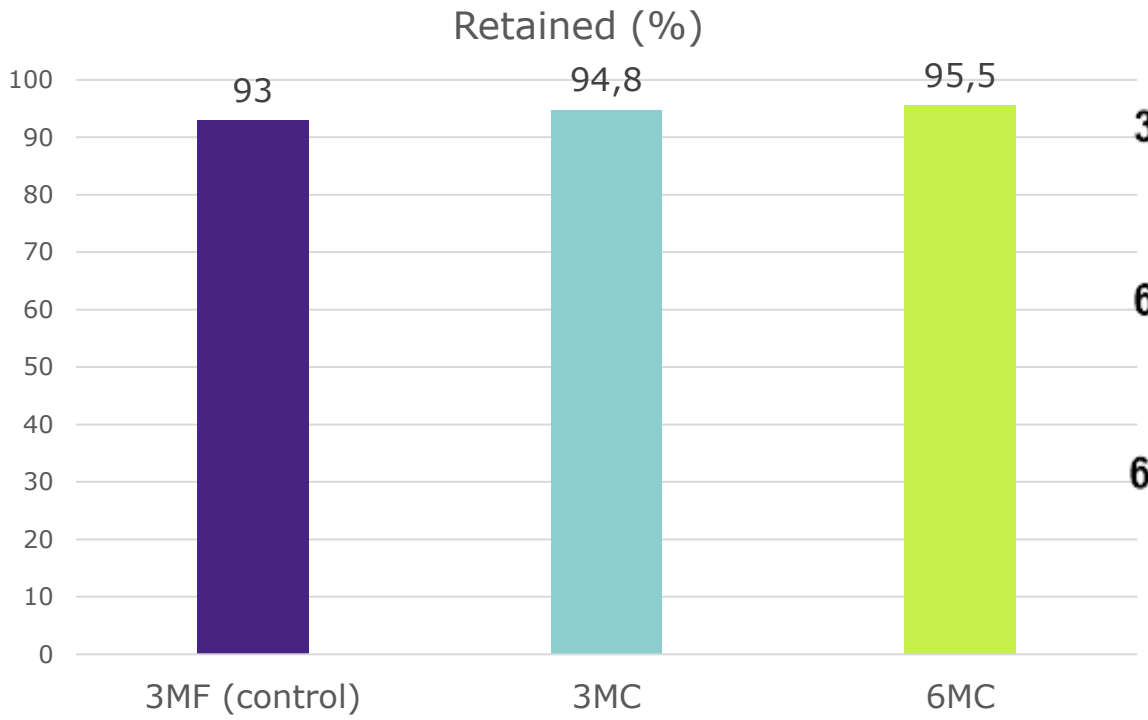
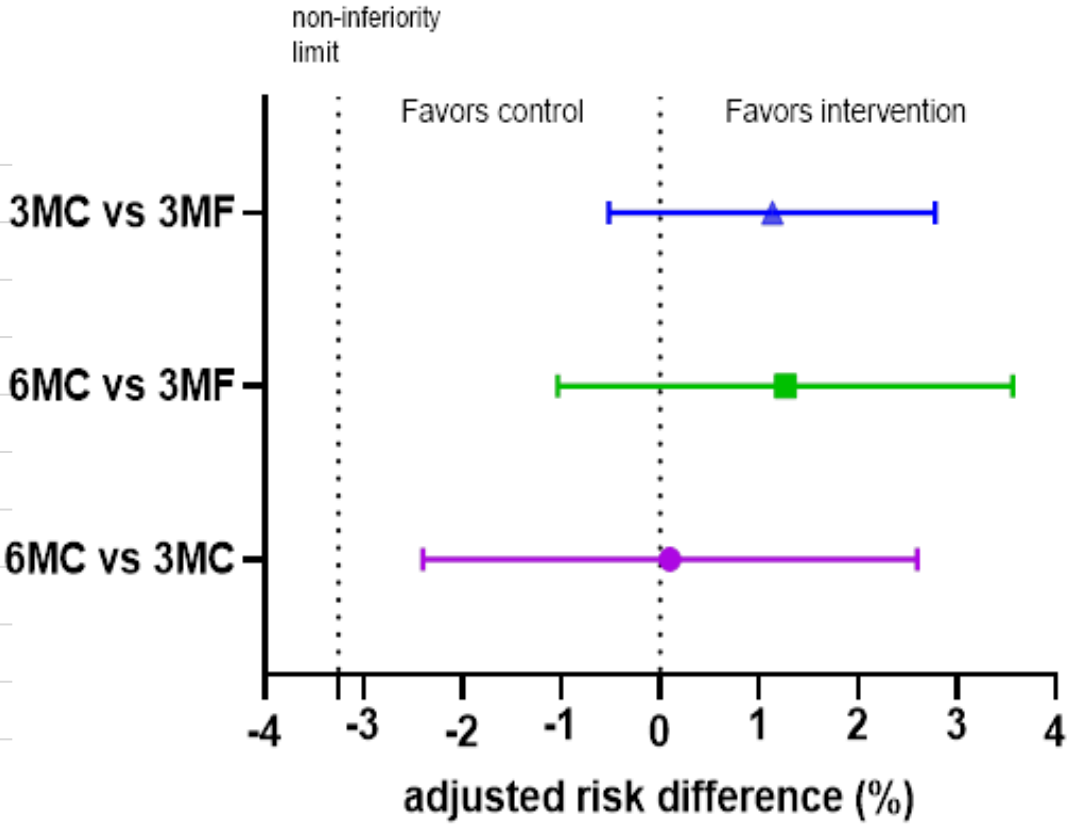
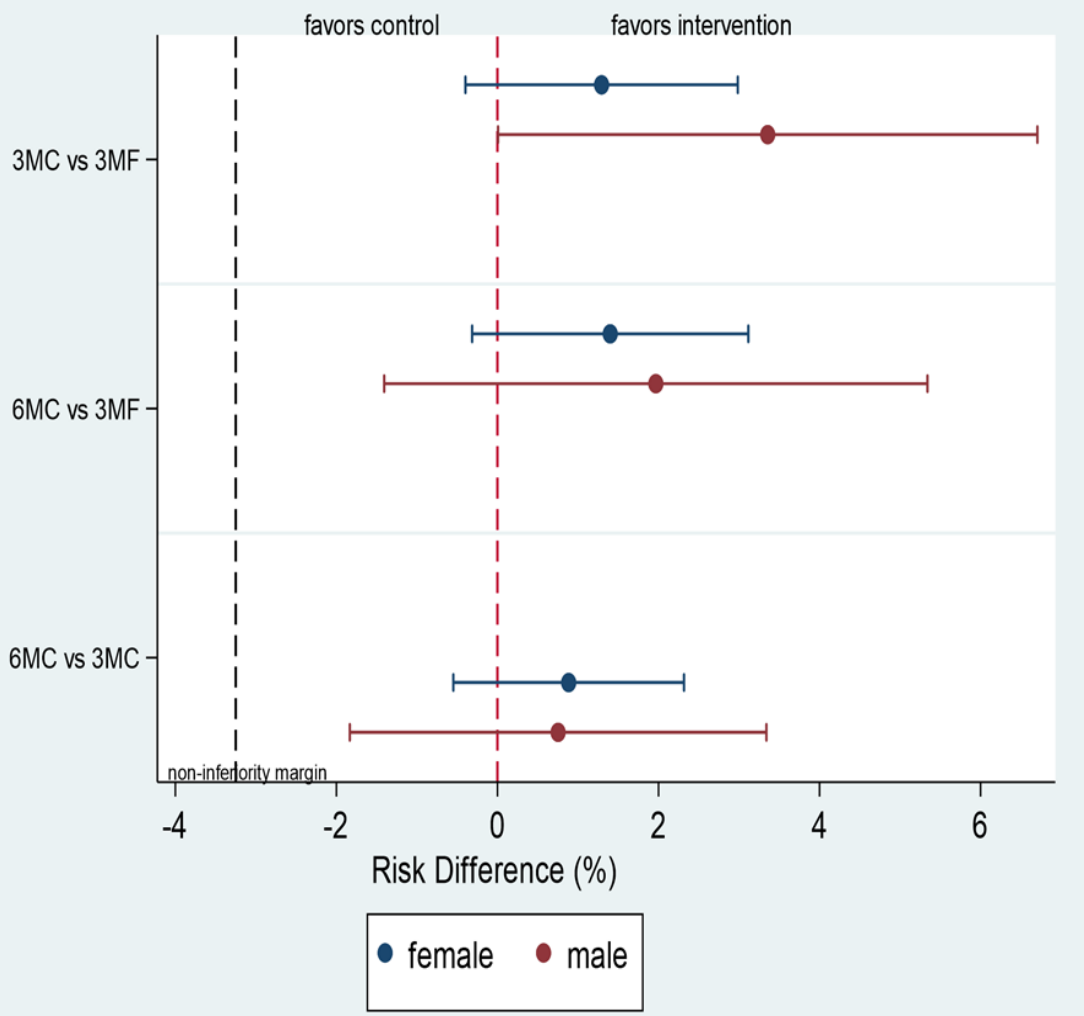
Overall retention in ART care



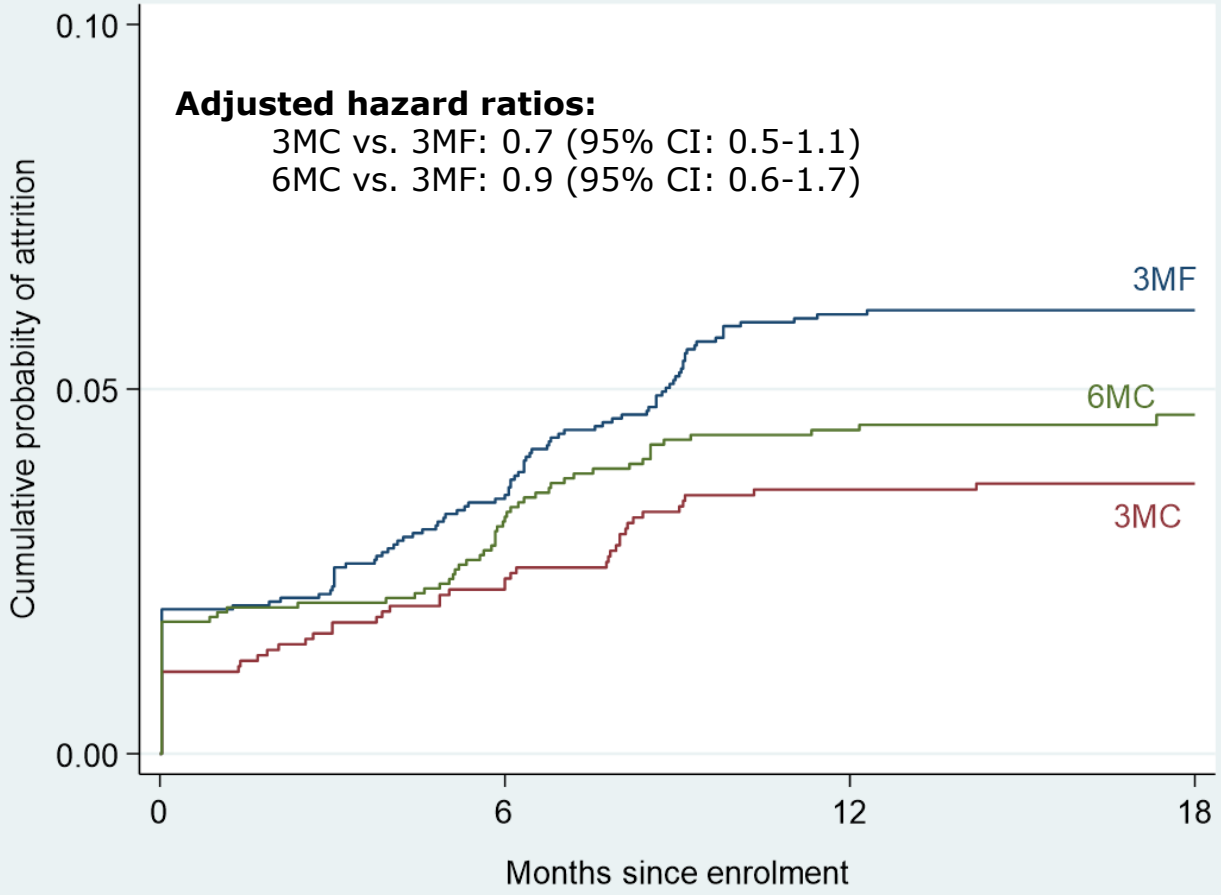


Only 1% of 3MC participants and 1% of 6MC participants needed to be referred back for facility-based care

Retention stratified by gender



18-month attrition from care (Zimbabwe)



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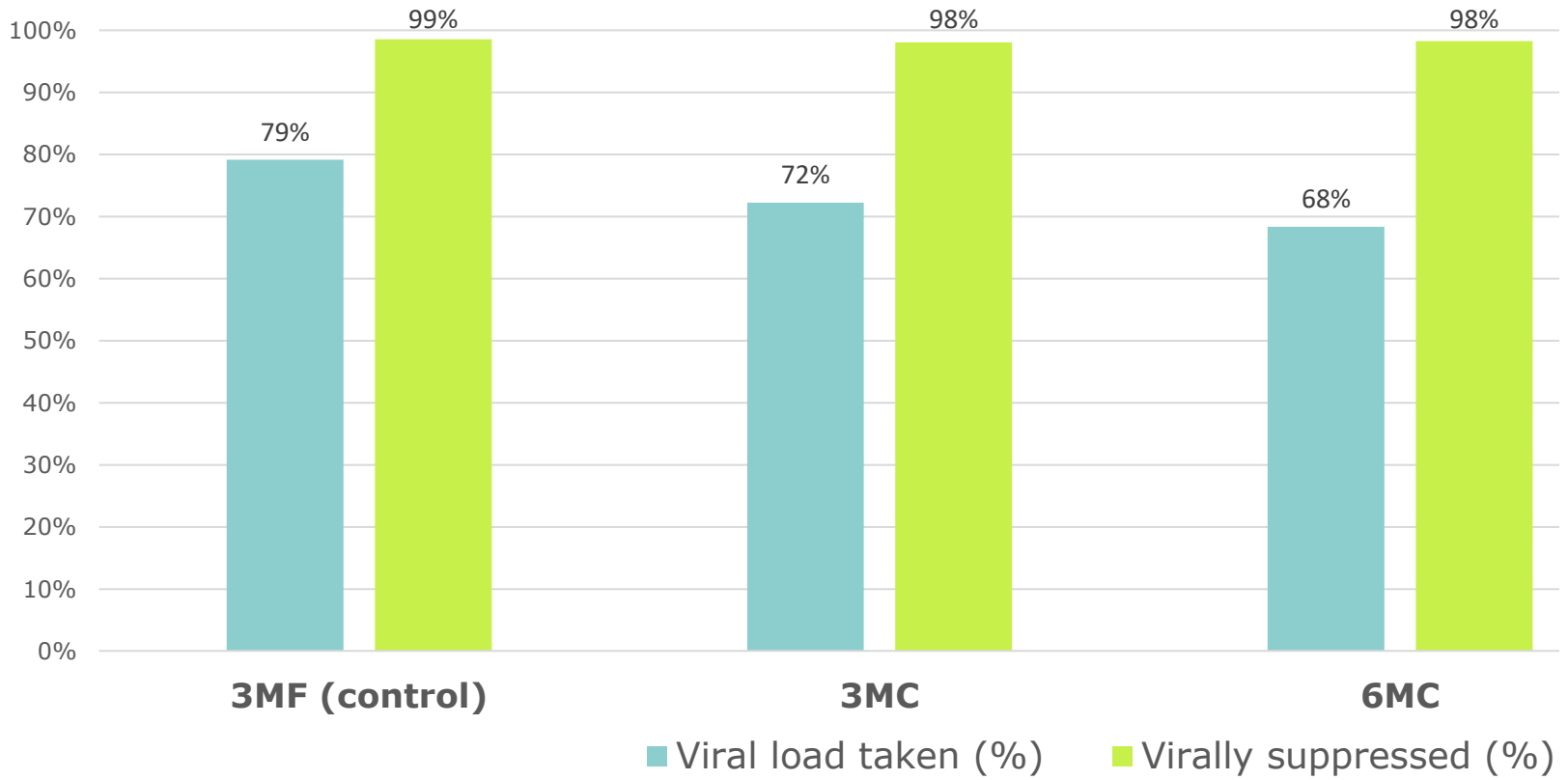
Overall viral load completion & suppression (12-months after enrollment)



- Viral load completion (68-79%)
- High viral suppression among those with a viral load

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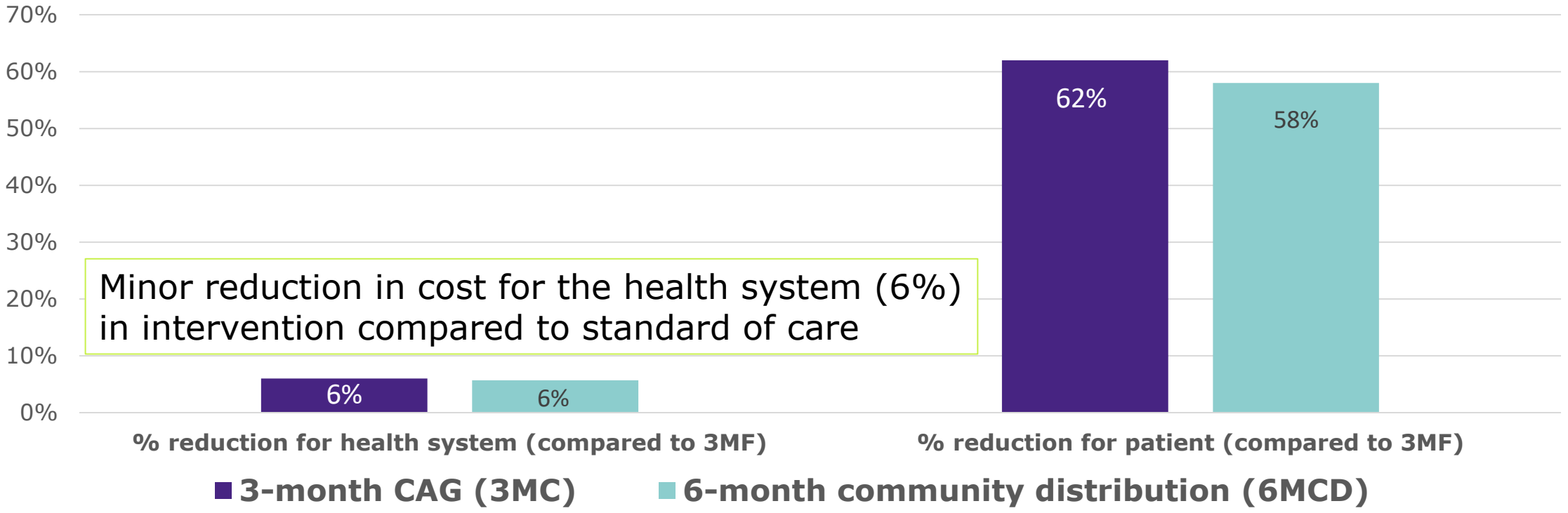
Results of cost analysis (Lesotho)

Significant reduction in cost for the patients (58-62%) in intervention compared to standard of care



Minor reduction in cost for the health system (6%) in intervention compared to standard of care

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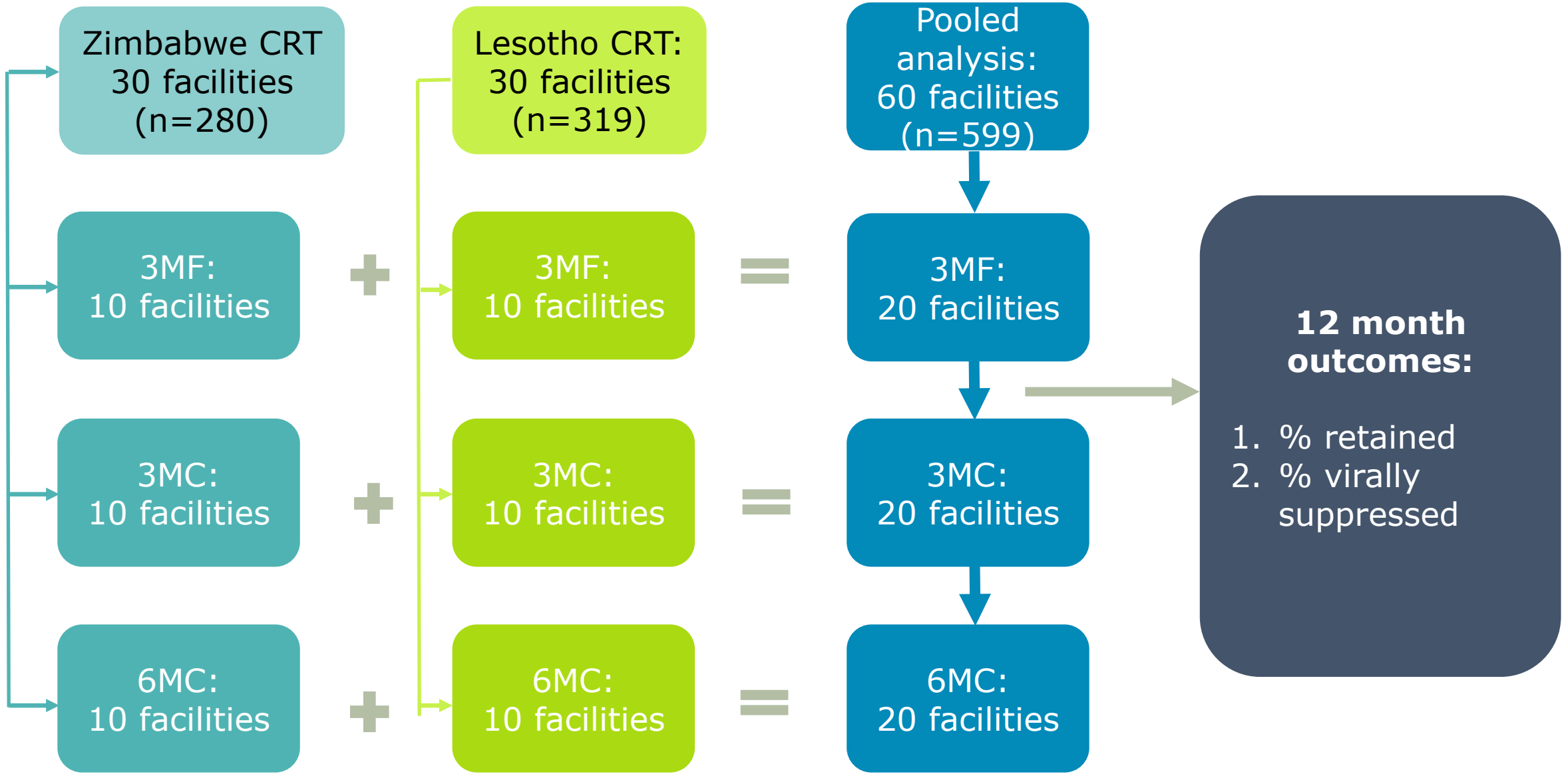
SUBGROUP ANALYSIS (pooled data)
Those initiated DSD 6-12 months after ART initiation



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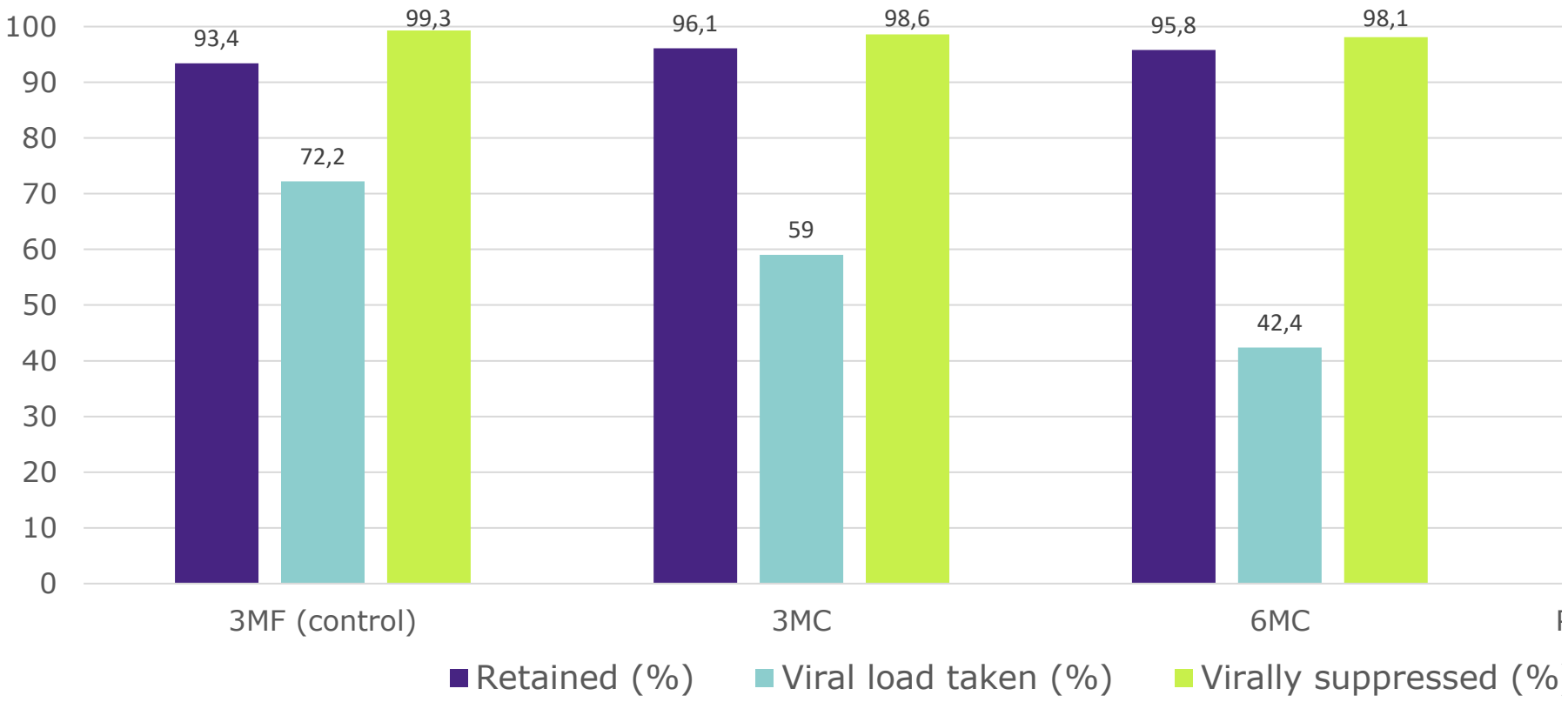
Outcomes (at 12 months) amongst those initiating DSD 6-12 months after ART initiation



- High retention
- Viral load completion (42-72%)
- High viral suppression among those with a viral load

Arm comparison of retention at 12 months among those with early referral to a DSD model

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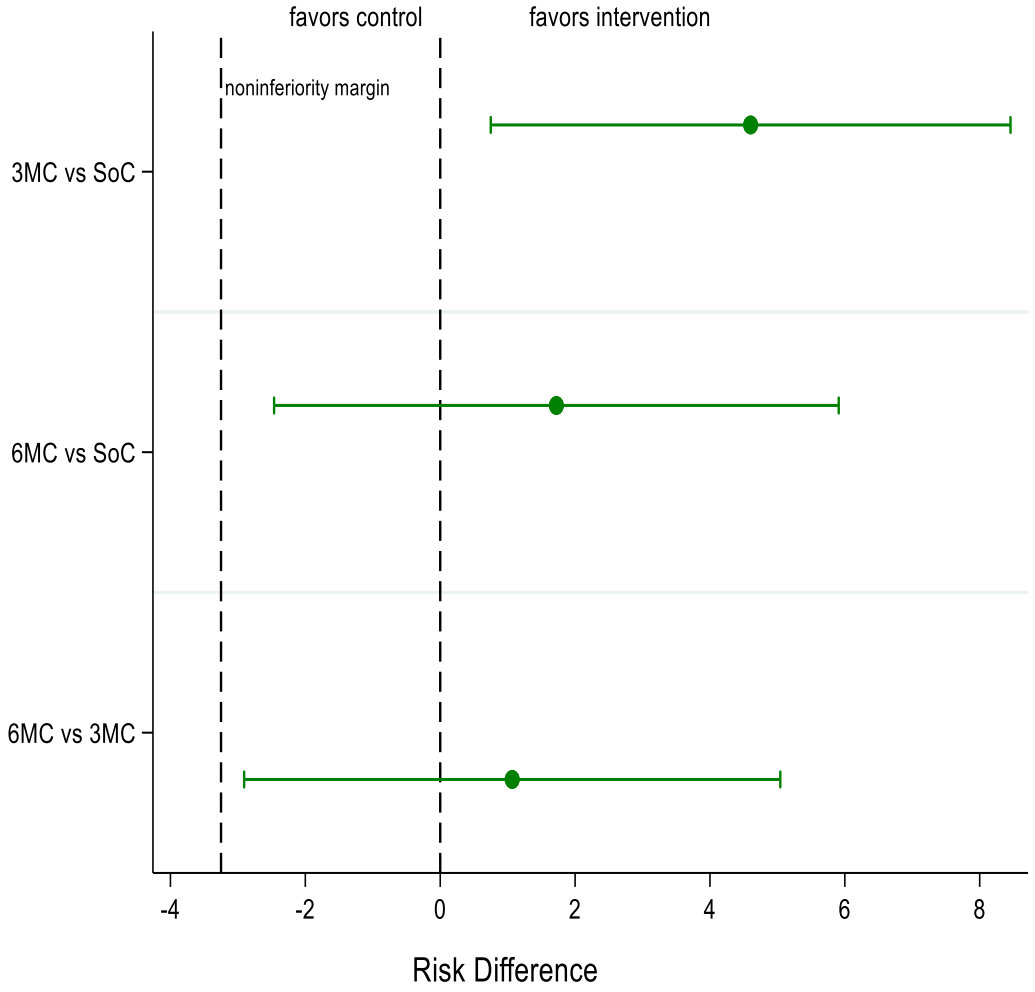
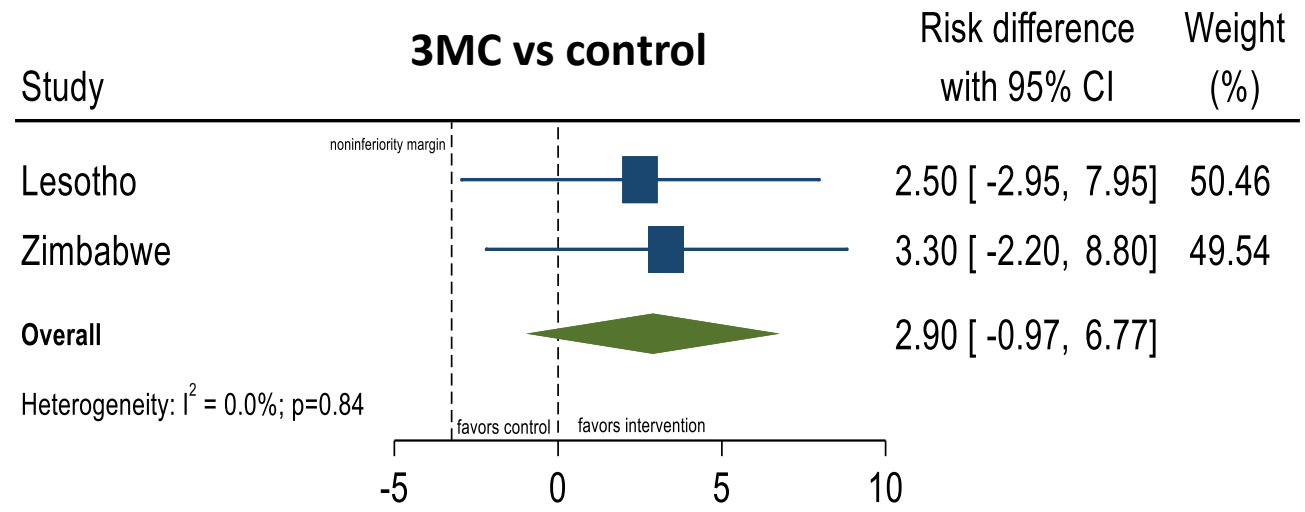
One stage IPD meta analysis

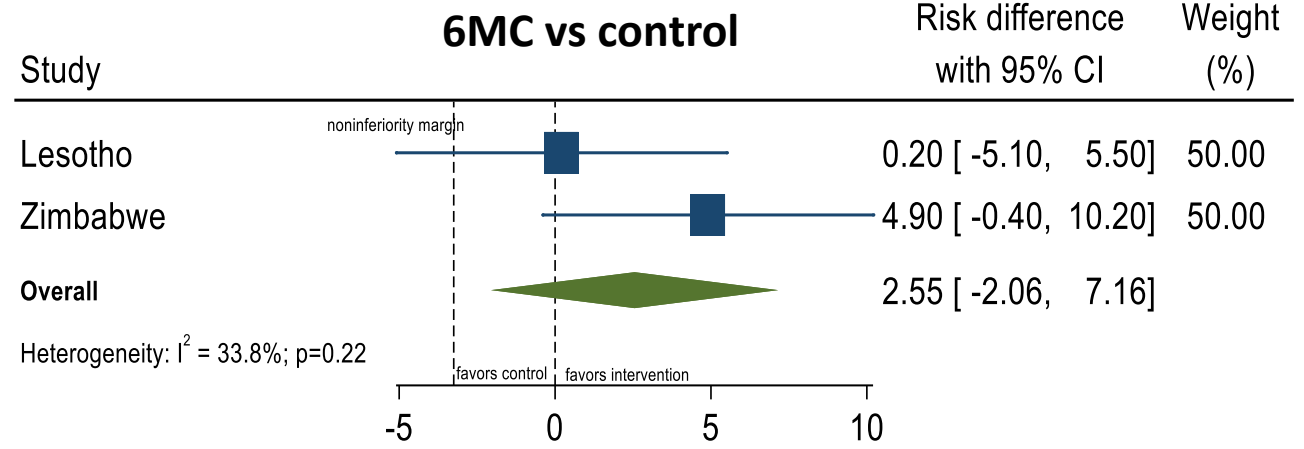


Analyses specified for clustering, and adjusted for trial and variables used in the stratified randomization

Two stage IPD meta analysis



Random-effects REML model



Random-effects REML model

Viral suppression comparison after 12 months amongst those initiating DSD within 12 months after ART initiation

	Adjusted risk ratio	
Arm	RR	95% CI
3MF (control)	Ref	-
3MC	0.98	0.92-1.03
6MC	0.98	0.95-1.00
3MC+6MC vs control	0.98	0.95-1.00

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Overall qualitative enquiry: participants and clinic staff

- Multiple benefits of MMD within CAGs
  - Decreased congestion in health facilities
  - Improved service delivery at clinics
  - Decline in staff burnout
  - Increased time availability for CAG members due to less time spent at clinics
  - Improved ART adherence
  - Improved social support experienced amongst members of CAGs.
- Challenges:
- The possibility of being exposed to HIV-related stigma when belonging to a CAG

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Strengths and limitations

Strengths

- Three-arm randomized design
- Large number of facilities included (30 per country)
- Studies incorporated into routine services (results generalizable)
- Clinical, cost and qualitative outcomes were assessed

Limitations

- Follow-up limited to 12-18 months
- Supoptimal viral load ascertainment after 12 months (due to limited viral load testing infrastructure)
- Small numbers of participants < 25 years included (particularly amongst those initiating DSD < 12 months after ART initiation)

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Conclusions

- **Community Adherence Groups (CAGs) receiving 3-6 months of ART were:**
  - Non-inferior to standard facility-based 3 monthly HIV visits in terms of retention in care and viral load suppression
  - Small cost savings to providers and substantial cost savings for patients
  - Suitable for newly stable people receiving ART for 6-12 months (aged ≥ 25 years).
  - Highly acceptable for both participants and healthcare staff.
- Small numbers of DSD participants needed to be referred back for clinic-based care.
- Community-based models of DSD for HIV treatment can be implemented to decongest healthcare facilities and promote social distancing in the COVID-19 era

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- Participants and health facility staff

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