IMPROVING RE-ENGAGEMENT IN TREATMENT FOR MEN LIVING WITH HIV IN MALAWI: COMPARISON OF TWO TRIALS

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Objective

We report and compare results from two trials to examine the impact of male-specific interventions on men's ART (re-)initiation in Malawi

Background

- Men in sub-Saharan Africa experience disparities in HIV outcomes [1]
- Treatment interruption (TI) is a major contributor to poor HIV outcomes among men living with HIV (MLHIV)
- Men experience unique barriers to antiretroviral therapy (ART) retention and may require male-specific interventions[2]
- **We use data from the ENGAGE and IDEaL randomized trials to examine the impact of male specific interventions for men**[3],
  - (ClinicalTrials.gov #NCT04858243 and #NCT051372100)

Methods

- **Design:** Unblinded, cluster randomized control trials (cRCT)
- **Eligibility Criteria:** MLHIV; ≥15 years; disengaged from HIV care (never initiated ART or currently experiencing TI after initiation); recruited through community tracing.
- **Enrollment Period and Sites:** August 2021-September 2022 from 22 high-burden health facilities across 8 districts in Malawi
- **Trial Arms:**
  - ENGAGE: randomized 1:1 to: 1) male-specific (MC) counseling + monthly home ART distribution for 3-months; or 2) Standard of Care (SOC) (generic counseling + facility ART distribution)
  - IDEaL: randomized 1:1:1 to: 1) MC + facility ART distribution; 2) MC + one-time home ART distribution; or 3) stepped services until clients achieved primary outcome, starting with MC + facility ART -> advanced psychosocial counseling -> one-time home ART
- **Primary Outcome for Parent Trials:** ART retention at 6 months
- **Process outcome for this analysis**: ART (re-)initiation at 2-month
- **Analysis:** 1) protocol driven analyses to compare outcomes within each trial, using intention-to-treat. 2) Ad-hoc analyses to compare interventions from IDEaL to SOC from ENGAGE trials.

Male-specific counseling alone, and combined with home-based ART improved men's ART (re-)initiation compared to standard of care in Malawi

Results

- 1149 MLHIV were enrolled in ENGAGE (n=634) and IDEaL (n=515)
- **Demographics:** Median 39 years of age, 93% ever initiated ART before

Table 1. Characteristics and process outcomes from ENGAGE and IDEaL trials (n=1149)

	ENGAGE Trial		IDeAL Trial		
	SOC n (%)	MC+ Home ART (3-month) n (%); aRR (95% CI)^	Male Counseling (MC) n (%); aRR (95% CI)^^	MC+ Home ART (1-month) n (%); aRR (95% CI)^^	Stepped MC + Home n (%); aRR (95% CI)^^
N	311	323	179	172	164
Demographics					
Median Age (IQR)	39 (32-46)	39 (31-47)	39 (31-46)	39 (32-46)	38 (33-45)
Previously initiated ART	297 (95.5)	304 (94.4)	163 (91.1)	156 (90.7)	156 (95.1)
Study Outcome					
Initiated	234 (75.2)	310 (96) 1.28*** (1.19-1.36)	173 (96.6) 1.28*** (1.16-1.42)	161 (93.6) 1.28*** (1.14-1.42)	160 (97.6) 1.30*** (1.17-1.43)
Unwanted status disclosure[ŧ]	4 (1.3)	3 (0.9)	4 (2.2)	1 (0.6)	2 (1.2)
Potential mediating factors					
Disclosure to Others	68 (21.9)	88 (27.2) 1.25 (0.95 - 1.64)	59 (33) 1.51** (1.10 - 2.07)	47 (27.3) 1.25** (1.02-1.52)	50 (30.5) 1.39** (1.03-1.88)
Internalized Stigma	150 (48.2)	139 (43) 0.89 (0.75 - 1.06)	59 (33) 0.68 (0.43 - 1.10)	46 (26.7) 0.89 (0.78 - 1.02)	57 (34.8) 0.72 (0.44 - 1.17)
Satisfaction with HCW interaction	-	307 (95)	178 (99.4)	169 (98.3)	161 (98.2)

^randomized comparison with SOC arm from ENGAGE Trial; ^^non-randomized comparison with SOC arm from ENGAGE Trial, adjusted for facility-level clustering

* p-value <0.01; **p-value <0.05; ***p-value <0.001; ŧ risk ratios not conducted due to small sample size in SOC arm or no SOC data

Results

- **Process Outcome:** (Re-) initiation at 2 months
  - **ENGAGE:** MC + home-based ART for 3-months significantly improved re-initiation as compared to SOC (96% vs 75% ; aRR:1.28 [95%CI 1.16 - 1.42])
  - **IDEaL:** No significant differences between interventions – all showed high rates of ART re-initiation (~95%)
  - **Adhoc comparison across ENGAGE and IDEaL:** IDEaL interventions significantly improved re-initiation as compared to ENGAGE SOC (~95 vs. 75%; aRR range: 1,28-1.30)
- Home ART does not seem to improve re-initiation over only offering MC
- **Mediating Factors:** MLHIV in intervention arms across trials reported higher rates of HIV status disclosure and lower rates of internalized stigma compared to MLHIV in the ENGAGE SOC arm
- **Acceptability:** Client satisfaction and perceived quality of care was high across intervention arms

Conclusions

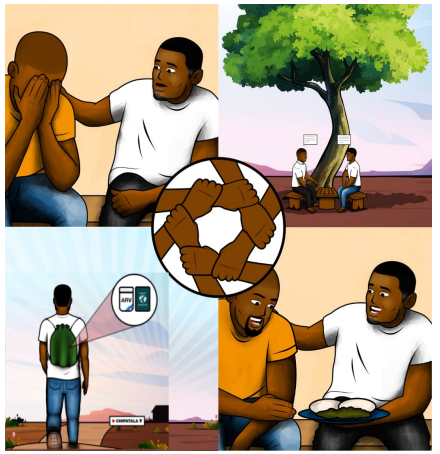
Male-specific counseling alone, and combined with home-based ART improved men's ART (re-)initiation compared to SOC in Malawi. Longer term outcomes are needed to indicate if ART gains will be sustained.

Acknowledgements

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References

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