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Outcomes of adults with HIV receiving TB preventive therapy in Kampala, Uganda

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BACKGROUND

- After decades of underuse, in 2020, TB preventive therapy (TPT) underwent rapid scale-up in Uganda as part of a national campaign
  - National scale-up of TPT overlapped with a trial comparing the impact of two TB screening strategies on TPT uptake and clinical outcomes among PWH
  - Selection and monitoring for individuals receiving TPT via the study protocol and routine care differed
- **Study Objective:** To compare outcomes for trial participants who received study- vs. clinic-initiated TPT

METHODS

- **Study Design:** TB SCRIPT (**TB SCR**eening **I**mproves **P**reventive **T**herapy Uptake) is a Phase 3 RCT (NCT04557176) comparing impact of two WHO-approved TB screening strategies on clinical outcomes of PWH
- **Participants:** Outpatients (≥18 years) new to HIV care
- **Setting:** 4 HIV clinics in Kampala, Uganda
- **Study Procedures*:***
  - 3HP patient selection: All participants underwent systematic TB screening by their trial arm
    - All screen-positives → TB confirmatory testing
    - All screen-negatives → assessed for 3HP eligibility using a standardized questionnaire, followed by LFT testing *Eligible participants with AST and ALT ≤3x ULN were prescribed 3HP 2 weeks after ART initiation*
  - 3HP monitoring: Monthly in-person visits for standardized assessment of side effects, adherence, TB symptoms
- **Clinic Procedures:**
  - TPT patient selection: Selection of patients for clinic-initiated TPT (IPT or 3HP) was at the discretion of routine clinic doctors, typically 3+ months after ART initiation
  - TPT monitoring: At the discretion of routine clinic doctors; TPT completion assessed by recall at end of treatment
- **Analysis:**
  - Excluded participants diagnosed with TB disease prior to TPT initiation
  - Compared baseline patient characteristics, % completing TPT, TB incidence, and mortality among participants who received study- vs. clinic-initiated TPT

Scale-up of TB preventive therapy is feasible, and should include protocols for standardized patient selection and monitoring

RESULTS

	Study-initiated TPT N=541	Clinic-initiated TPT N=250	p-value
Baseline characteristics			
Male sex	191 (35%)	100 (40%)	0.20
Median age, years (IQR)	30 (25-36)	31 (27-38)	0.01
Median CD4 count (IQR)	295 (172-474)	179 (69-269)	<0.01
Median BMI (IQR)	22.8 (20.7-25.7)	22.1 (19.9-24.8)	0.02
Diabetes	2 (0.4%)	3 (1%)	0.18
Pregnant at baseline	0 (0%)	43 (17%)	<0.01
Prior TB	9 (2%)	2 (1%)	0.30
TB screen-positive	0 (0%)	189 (76%)	<0.01
TPT initiation & completion			
Median days to TPT Initiation (IQR)	14 (14-15)	92 (90-175)	<0.01
Initiated 3HP vs. IPT	541 (100%) vs. 0 (0%)	17 (6.8%) vs. 223 (93.2%)	<0.01
Completed TPT	511 (94.5%)	206 (82.4%)	<0.01

RESULTS

	Study-initiated TPT N=541	Clinic-initiated TPT N=250	p-value
Incident TB[1]	9 (1.7%)	8 (3.2%)	0.19
Microbiologically confirmed	2 (0.4%)	5 (2.0%)	0.04
Median days from TPT initiation to TB disease (IQR)	561 (359-763)	609 (491-623)	1.00
Clinically diagnosed	7 (1.3%)	3 (1.2%)	1.00
Median days from TPT initiation to TB disease (IQR)	217 (55-483)	432 (316-498)	0.27
Died[3]	4 (0.7%)	4 (1.6%)	0.30
Median days from TPT initiation to death (IQR)	369 (277-464)	126 (83-168)	0.03

[1]All with microbiologically-confirmed TB completed TPT; 3 clinically diagnosed with TB during study-initiated TPT
[2]No deaths were classified as likely due to TB; one clinic-initiated death was due to possible TPT-related drug toxicity

CONCLUSIONS

- Participants who initiated TPT through the trial had lower TB incidence and mortality than those who initiated TPT through routine care. Better outcomes were likely due to:
  - Study-initiated TPT participants had less advanced HIV and screened negative for TB at ART initiation
  - Higher TPT completion rates among participants receiving study-initiated TPT
  - Presence of standardized protocols for TPT patient selection and TPT monitoring
- To maximize the potential of TPT, scale-up should include implementation of protocols to standardize patient selection and monitoring and to improve TPT adherence

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