Project Brief: PALESA

Full Title of Study/Programme	A Pilot Randomized Controlled Trial to Assess a Model of Decentralised STI-Self Testing and Risk Self-Assessment Among Adolescent Girls and Young Women in South Africa to Trigger PrEP Re-start
Technical Focus Area/Key Words	Sexually transmitted infections, point of care testing, risk assessment PrEP, PrEP restart,
Rationale	In South Africa (SA), adolescent girls and young women (AGYW) experience high rates of incident HIV infection. HIV pre-exposure prophylaxis (PrEP) has the potential to impact HIV incidence when used with consistent adherence to the required dosing schedule. Daily oral PrEP adherence and persistence in PrEP programs have been shown to be challenging for AGYW <25 years old. Reasons for non-use or discontinuation vary and include product-related issues, individual user issues and social network issues. One frequently reported response was low perceived risk of HIV acquisition. It is therefore crucial to empower AGYW to recognize periods of heightened HIV risk in their lives and to seek care and facilitate improved use of PrEP during these times. Curable bacterial STIs increase risk of HIV transmission and SA has relatively high prevalence rates of Chlamydia trachomatis (CT), Neisseria gonorrhea (NG) and Trichomonas vaginalis (TV) among women aged 15–24 years. These STIs can also have severe effects on sexual, reproductive, and general health as well as cause social harms. Effective STI identification and management is therefore vital. Self-testing has been a trail blazer in the HIV testing world alleviating stigma associated to testing and offering the convenience of discrete testing in less private settings. Self-testing options for STIs would appear the next logical innovation however these options are not yet available. There is however potential for AGYW to use commercially available NG, CT and TV rapid test kits to self-test for STI, based on recent studies showing high rates of acceptability and feasibility of self-collected swabs for STI testing.
Primary Objectives	• To determine the feasibility and acceptability of conducting a randomized controlled trial (RCT) among South African AGYW to determine the impact of STI self-testing coupled with a self-administered behavioural risk assessment on restarting PrEP relative to a self-administered behavioural risk assessment only • To assess AGYW acceptability of and experiences with use at-home STI testing, self-administered behavioural risk assessment, and re-starting PrEP while participating in the pilot RCT
Secondary Objectives	Not applicable
Tertiary Objectives	Not applicable

Primary Endpoints/Outcomes	• Feasibility of study implementation including attainment of operational metrics as per below
	  ○ Recruitment target achieved
	  ○ High retention rate maintained (≥ 90%)

	○ Participants are able to assess their risk of acquiring HIV by self-testing for STIs and/or completing a self-administered behavioural risk assessment ○ Frequency of oral PrEP restarting ○ PrEP continuation 1 month after re-start ○ High frequency of all research procedures are completed • Data collected on experiences of at-home STI testing, self-administered behavioural risk assessment, and re-starting PrEP while participating in the pilot trial
Secondary Endpoints/Outcomes	Not applicable
Tertiary Endpoints/Outcomes	Not applicable
Study Design	Pilot RCT with nested qualitative component (In-Depth Interviews at study exit))
Study arms	• STI self-test kits (NG, CT and TV) with in-person instruction at enrolment and telephone/video-based instructions for home use coupled with self-administered behavioural risk assessment • Self-administered behavioural risk assessment only (standard of care)
Study population	AGYW aged 16-20, non-pregnant, HIV negative who discontinued PrEP use within the past 6 months
Study sample size	~50 AGYW (55)
Follow up/duration	6 months per AGYW
Study/Programme sites	Hillbrow, Johannesburg
Study/Programme duration	~36 months
Intervention	Visby Sexual Health test kits and self-administered risk assessment
Operations	Not applicable
Investigators	Dr. Thesla Palanee-Phillips, Principal Investigator (PI), Wits RHI Ms. Krishnaveni Reddy, Co-PI, Wits RHI Prof. Renee Heffron, Co-PI, University of Alabama at Birmingham
Other Partners & Collaborators	Mr. Siyanda Tenza, Co-investigator, Wits RHI Dr. Jennifer Velloza, Co-Investigator, University of California, San Francisco
Linked Sub Studies and post grad projects	Not applicable
Publications/key presentations to date	Not applicable
Progress Update	Formative research complete Clinical study implemented on 01 July 2023 • Accrual complete: 55 participants enrolled • Study exits: 26/55
Frequency of donor narrative report	Annual
Overall Project Contact	Dr. Thesla Palanee-Phillips
Briefing owner and date	Krishnaveni Reddy, 28 March 2024